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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Legislation and Regulation Committee

Robert Graul, RPh, Chair
Robert Swart, PharmD
Shirley Wheat, Public Member
Andrea Zinder, Public Member

LEGISLATION AND REGULATION COMMITTEE REPORT AND ACTION

Report of the Legislation and Regulation Committee Meeting of January 7, 2009

A. REGULATION REPORT AND ACTION

1. Regulations Adopted by the Board

Action Required – Action to Amend Title 16 CCR Section 1760 – Disciplinary Guidelines

Attachment A-1

Committee Recommendation – Move forward with a 15-day notice as recommended by staff.

Proposed Amendment to Title 16 CCR §1760 – Disciplinary Guidelines

At the April 2008 Board Meeting, the board voted to adopt a regulation change to amend Title 16 CCR §1760 – Disciplinary Guidelines. During discussion at this Board Meeting, counsel recommended that the board add several responses to comments submitted during the written comment period. Staff received these comments and included responses in the completed rulemaking, which was submitted to the Department of Consumer Affairs (department) on September 12, 2008.

While the department did approve this regulation, State and Consumer Services Agency (agency) is concerned about the "Option" language relating to automatic revocation when a probationer fails to submit cost recovery as mandated. As a result, it is being brought back to the board for further consideration.

To allow the board to continue to pursue the regulation change and obtain agency approval that will be required to move forward with the regulation, the board will need to (1) withdraw the rulemaking and begin over or (2) seek a 15-day notice removing this specific term. Either action will require a vote from the full board at the January 2009 Board Meeting to proceed.

Below is the term in question. The objection raised is to the "Option" language.

As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of $_____. Respondent shall make said payments as follows: _____. There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.
The filing of bankruptcy by respondent shall not relieve respondent of his or her responsibility to reimburse the board its costs of investigation and prosecution.

Option: If respondent fails to make any payment by the directed deadline(s), the stay shall terminate and the license shall be revoked without further notice or opportunity to be heard.

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2. **Action Required** -- Action to Repeal Title 16 CCR Sections 1716.1 and 1716.2, Adopt Sections 1735-1735.8, and Amend Sections 1751-1751.8 Regarding Requirements for Pharmacy Compounding and Sterile Injectable Compounding

Attachment A-2

Subcommittee Recommendation – To amend § 1735.3 as proposed in the rule making to include the following: [Full text provided in Attachment 1]

(a)(6) The manufacturer and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

Currently, pharmacy law provides the authority for a pharmacist to compound drug products as well as compound sterile injectable products. As required in Business and Professions Code section 4127, the board adopted regulations to implement the provisions for pharmacies that compound sterile injectable products. There are no similar provisions in regulation to detail the requirements for pharmacies that complete general compounding. This proposal would establish guidelines to provide uniformity in compounding for California consumers.

The 45-day comment period began in September 2008 and a regulation hearing was held at the October 2008 Board Meeting. At the conclusion of the regulation hearing, the board voted to create a subcommittee of two board members to work with staff and fully consider all comments received both orally and in writing.

3. **Regulations Previously Adopted by the Board – No Action Required**

a. ***INFORMATION ONLY*** - Amend Title 16 CCR §1773 and Adopt § 1773.5 – Establishment of an Ethics Course as an Optional Enforcement Component for Discipline

Attachment A-3

In April 2007, the board established a subcommittee to examine the development of an ethics course for pharmacists as an enforcement option as part of discipline. Based on the work of this subcommittee, the subcommittee recommended to the full the board that it vote to create a program similar to the program used by the Medical Board. This proposal would establish in regulation the minimum requirements for the ethics program. These minimum requirements are designed to better guide the board and licensees in the selection of an ethics course and to ensure that the course will satisfy the minimum requirements intended in the section. This proposal will provide licensees with the necessary information to assist in their rehabilitation.

The board determined that minimum requirements are necessary, based on testimony received during the October 2007 Board Meeting. During the meeting, the board received testimony from the Institute for Medical Quality (IMQ), the course provider for the Medical Board's ethics course. The board determined that a minimum of 14 direct contact hours is appropriate to allow for case presentations, group discussion and experiential exercises and role-playing to ensure sufficient time to discuss and evaluate situations. In addition, based on the recommendation of the IMQ, the board's proposal incorporated an additional 8 hours of time to allow the pharmacist to complete self-reflection on the decisions made that led to the violations and ultimate referral to the program and post-classroom instruction for up to one year. This self-reflection includes completing questions as part of a background assessment. The two post-course longitudinal studies ensure that the pharmacist has successfully internalized the necessary changes to prevent future violations resulting from unethical behavior.

During the October 2008 board meeting, the board held a regulation hearing on the proposed changes. At the conclusion, the board directed staff to take all steps necessary to complete the rulemaking process, including the preparation of modified text for an additional 15-day comment period and to take specific action if no adverse comments were received.

Amendment:

Change the word "medicine" to "pharmacy" at proposed §1773.5(a)(5)(B)

If, after the 15-day public comment period, no adverse comments are received, authorize the Executive Officer to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt amendments to §1773 as filed and adopt §1773.5 of the proposed regulations with this modified text.

The 15-day comment period is over and no additional comments were received. Board staff will begin compiling the rulemaking and will submit it to the department during the first quarter of 2009.

b. ***INFORMATION ONLY*** - Amend Title 16 CCR §1715 – Self Assessment Forms for Community and Inpatient Pharmacies

Section 1715 establishes requirements for the pharmacist-in-charge (PIC) of a licensed pharmacy to complete a self-assessment form to ensure compliance with pharmacy law.

These self-assessment forms are designed to assist pharmacies in increasing their compliance with legal requirements and, therefore, increase public safety. Additionally, the forms make the pharmacy inspection process more meaningful and provide relevant information to pharmacies and their PIC.

The law requires that the self-assessment form be completed by July 1 of every odd numbered year as well as whenever a change in the PIC occurs.

As these forms are incorporated by reference in section 1715, the board must pursue a regulation change to require use of the updated forms.

At the October 2008 Board meeting, the board voted to pursue section 100 changes to update the forms. Board staff will be pursuing the section 100 changes the first quarter of 2009 to ensure approval in advance of the July 1, 2009 completion date.

c. ***INFORMATION ONLY*** - Amend Title 16 CCR §1784 – Self Assessment Form for Wholesalers

Section 1784 establishes the requirement for the designated representative-in-charge (DRC) of a licensed wholesaler to complete a self-assessment form to ensure compliance with pharmacy law. These self-assessment forms are designed to assist wholesalers in increasing their compliance with legal requirements and, therefore, increase public safety as a result of this compliance. Additionally, the forms make the inspection process more meaningful and provide relevant information to wholesalers and their DRC.

The law requires that the self-assessment form be completed by July 1 of every odd numbered year as well as whenever a change in the DRC occurs.

As this form is incorporated by reference in section 1784 the board must pursue a regulation change to require use of the updated form.

At the October 2008 Board meeting, the board voted to pursue section 100 changes to update the form. Board staff will be pursuing the section 100 changes the first quarter of 2009 to ensure approval in advance of the July 1, 2009 completion date.

4. Board Approved Regulations Awaiting Notice – No Action Required

a. ***INFORMATION ONLY*** - Proposed Addition to Title 16 CCR §1785 – Self-Assessment of a Veterinary Food-Animal Drug Retailer

Attachment A-4

The adoption of Section 1785 of the California Code of Regulations would establish a self-assessment form for veterinary food-animal drug retailers and require the designated representative-in-charge to complete this form to ensure compliance with pharmacy law. This form would also aid these licensees in complying with legal requirements of their operations and therefore increase public safety as a result of this compliance.

The draft form was reviewed and approved at the September 2007 Enforcement Committee Meeting. During the October 2007 Board Meeting, the board voted to approve the regulation for the 45-day comment period.

The Licensing Committee is completing a program review of the Veterinary Food-Animal Drug Retailer program. A copy of the draft language and form is provided in Attachment 3; however, board staff do not anticipate proceeding with this regulation change until the Licensing Committee completes its review of the Veterinary Food-Animal Drug Program for possible changes.

b. ***INFORMATION ONLY*** - Proposed Adoption of Title 16 CCR §1751.8 – Accreditation Agencies for Pharmacies that Compound Sterile Injectable Drug Products **Attachment A-5**

Business and Professions Code section 4127.1 requires a separate license to compound sterile injectable drug products. Section 4127.1(d) provides exemptions to the licensing requirement for pharmacies that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board. Since the inception of this statute, the board has approved two such agencies.

This proposed regulation would specify the criteria the board uses to evaluate these agencies.

c. Proposed Amendment to Title 16 CCR §§1721 and 1723.1 – Dishonest Conduct on a Pharmacist Licensure Examination/Confidentiality

Attachment A-6

At the October 2007 Board Meeting, the board voted to approve proposed amendments to Title 16 CCR §§1721 and 1723.1 that would strengthen the penalty an applicant would incur for dishonest conduct during an examination as well as further clarify the penalty an applicant would incur for conveying or exposing any part of the licensing examination.

This recommendation was generated from the board's Competency Committee, which is responsible for the development of the CPJE examination. According to the board's current exam psychometrician, the cost to generate a new test item is $2,000/item. Compromised test items pose not only a financial loss to the board, but also inhibit the board's ability to test for minimum competency, and if an otherwise incompetent applicant passes the exam because the exam has been compromised, such a breach is a public safety issue.

5. Regulations Under Development – No Action Required

a. ***INFORMATION ONLY*** - Proposed Amendment to Title 16 CCR §1780 – Update the USP Standards Reference Material

Title 16 CCR §1780 sets minimum standards for drug wholesalers. Section 1780(b) references the 1990 edition of the United States Pharmacopeia (USP) Standards for temperature and humidity. The USP Standards is updated and published annually. Consequently, this section requires an amendment to CCR §1780(b) to reflect the 2005 version of the publication and to hold wholesalers accountable to the latest standards if determined appropriate.

Because of stated concerns about whether referencing the 2005 USP standards is an unreasonable burden on wholesalers, the board voted at the October 2008 Board Meeting to address the issue of updating the USP Standards reference materials within this section.

President Ken Schell and Committee Chair Bob Graul are serving on the subcommittee and will be working with board staff and industry to address potential concerns. To that end, at the January 2009 Legislation and Regulation Committee Meeting, Chairman Garul requested volunteers to work with the subcommittee. Kaiser, California Society of Health-Systems Pharmacist and Western Medical Center Santa Monica will have representatives on the subcommittee. Ms. Giny Herold will also contact HDMA for volunteers.

b. ***INFORMATION ONLY*** - Proposed Amendment to Title 16 CCR §1732.2 – Continuing Education for Competency Committee Members

At the October 2008 Board Meeting, the board voted to award to Competency Committee members up to six hours of continuing education (CE) credit annually to complete on-line review of examination questions should the committee member not seek reimbursement from the board for their time associated with this function.

Competency Committee members serve as the board's subject matter experts for the development of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). A committee member's term is generally about eight years.

Annually, committee members attend approximately 3-4 two-day meetings to assist in examination development. Each two-day meeting consists of approximately 2-4 hours of preparation time in addition to 16 hours of meeting time. Committee members also participate in 2-4 writing assignments based on the examination development need. Committee members spend approximately 50-80 hours preparing for and attending committee meetings on an annual basis in addition to multiple writing assignments and are compensated for time and travel.

One of the core functions of this committee is to complete an on-line review of all test questions prior to administration. As the test questions cover all aspects of pharmacy practice and law, this on-line review requires a significant amount of committee time to research items and confirm that a question and answer are valid. Given this, the committee requests that the board award up to six hours of CE annually for members that complete this on-line review. (Typically, committee members are not compensated for their time to complete this function. If a committee member is seeking reimbursement for this time, however, continuing education will not be awarded.)

Current pharmacy law requires pharmacists to earn 30 hours of approved CE every two years as a condition of license renewal. Currently, pharmacists can earn CE

- Offered by approved providers (ACPE and the Pharmacy Foundation of California – 16 CCR 1732.05)
- Approved by Medical Board, Board of Podiatric Medicine, Board of Registered Nursing or Dental Board, if relevant to pharmacy practice (16 CCR 1732.2), and/or
- By petition of an individual pharmacist for a course that meets board standards for CE for pharmacists (16 CCR 1732.2)

Additionally, the board will award CE for

- Attending one board meeting annually (6 hours of CE)
- Attending two committee meetings annually (2 hours of CE for each meeting, must be different committee meetings), and
- Completing the PSAM, which is administered by the National Association of Boards of Pharmacy (6 hours of CE)

Board staff will be drafting regulation language for board consideration.

Attachment A-1

Proposed Amendment to Title 16 CCR § 1760 Disciplinary Guidelines

(Text follows next page)

DEPARTMENT OF CONSUMER AFFAIRS
STATE BOARD OF PHARMACY

DISCIPLINARY GUIDELINES
(Rev. ~~1/2001~~10/2007)

INTRODUCTION

The Board of Pharmacy (board) is responsible for the enforcement of statutes and regulations related to the practice of pharmacy (the Pharmacy Law) and to the regulation of controlled substances (the Uniform Controlled Substances Act). The board serves the public by:

- protecting the health, safety, and welfare of the people of California with integrity and honesty;
- advocating the highest quality of affordable pharmaceutical care;
- providing the best available information on pharmaceutical care; and
- promoting education, wellness and quality of life.

Pharmacists are patient advocates who provide pharmaceutical care and exercise clinical judgment for the citizens of California, enlightening them about their drug therapy through effective communicating and listening, assessing, collaborating, understanding and intervening. ~~In addition, e~~Enforcement officials ~~are provided the resources to~~ act quickly, consistently and efficiently in the public's interest to ensure the safe, effective delivery of these services.

The board recognizes the importance of ensuring the safe and effective delivery of dangerous drugs and controlled substances for therapeutic purposes. At the same time, and given the historical and current abuse and diversion of drugs, particularly controlled substances, the board believes there should be no tolerance for licensees who traffic in drugs or who, in the absence of appropriate evidence of rehabilitation, personally abuse drugs or alcohol.

In accordance with ~~section~~ Section 1760 of the California Code of Regulations, the board has produced this booklet for those involved in and affected by the disciplinary process: the general public, attorneys from the Office of the Attorney General, administrative law judges from the Office of Administrative Hearings, defense attorneys, board licensees, the courts, board staff and board members who review and vote on proposed decisions and stipulations.

These guidelines are to be followed in Board of Pharmacy disciplinary actions. Subject to judicial review, the ~~T~~board has the final authority over the disposition of its cases, and, to complete its work, it uses the services of the Office of the Attorney General and the Office of Administrative Hearings. The board recognizes that individual cases may necessitate a departure from these guidelines. In such cases, the mitigating or aggravating circumstances shall be detailed in any proposed decision or any transmittal memorandum accompanying a proposed stipulation, especially where Category III violations are involved.

~~The board has found that accusations are rarely filed except in serious cases.~~ In general, the position of the board is that revocation should always be an option whenever grounds for discipline are found to exist. Board policy is that revocation is generally an appropriate order where a respondent is in default, such as when he or she fails to file a notice of defense or fails to appear at a disciplinary hearing.

Board policy is that a suspension, where imposed, should be at least 30 days for an individual and at least 14 days for a licensed premises.

The board seeks recovery of all investigative and prosecution costs up to the hearing in all disciplinary cases. This includes all charges of the Office of the Attorney General, including, but not limited to, those for legal services, and includes charges by expert consultants. The board believes that the burden of paying for disciplinary cases should fall on those whose conduct requires investigation and prosecution, not upon the profession as a whole.

The board recognizes there may be situations where an individual licensee deserves a stronger penalty than the pharmacy for which he or she works, but the board also believes in holding a pharmacy owner, manager, and/or pharmacist-in-charge responsible for the acts of ~~their employees who operate the~~ pharmacy personnel. Similarly, the board recognizes that in some cases a licensed premises may well be more culpable than any individual licensed by or registered with the board.

For purposes of these guidelines "board" includes the board and/or its designees.

Deletions to the regulatory text are indicated by double strike-through, thus: ~~deleted language~~. Additions to the regulatory text are indicated by a double underline, thus: added language

FACTORS TO BE CONSIDERED IN DETERMINING PENALTIES

Section 4300 of the Business and Professions Code provides that the board may discipline the holder of, and suspend or revoke, any certificate, license or permit issued by the board.

In determining whether the minimum, maximum, or an intermediate penalty is to be imposed in a given case, factors such as the following should be considered:

1. actual or potential harm to the public
2. actual or potential harm to any consumer
3. prior disciplinary record, including level of compliance with disciplinary order(s)
4. prior warning(s) ~~of record(s)~~, including but not limited to citation(s) and fine(s), letter(s) of admonishment, and/or correction notice(s)
5. number and/or variety of current violations
6. nature and severity of the act(s), offense(s) or crime(s) under consideration
7. aggravating evidence
~~7.~~8. mitigating evidence
~~8.~~9. rehabilitation evidence
~~9.~~10. compliance with terms of any criminal sentence, parole, or probation
~~10.~~11. overall criminal record
~~11.~~12. if applicable, evidence of proceedings for case being set aside and dismissed pursuant to ~~section~~ Section 1203.4 of the Penal Code
~~12.~~13. time passed since the act(s) or offense(s)
~~13.~~14. whether the conduct was intentional or negligent, demonstrated incompetence, or, if the respondent is being held to account for conduct committed by another, the respondent had knowledge of or knowingly participated in such conduct
~~14.~~15. financial benefit to the respondent from the misconduct.

No single one or combination of the above factors is required to justify the minimum and/or maximum penalty in a given case, as opposed to an intermediate one.

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MITIGATING EVIDENCE

A respondent is permitted to present mitigating circumstances at a hearing or in the settlement process and has the burden of demonstrating any rehabilitative or corrective measures he or she has taken. The board does not intend, by the following references to written statements, letters, and reports, to waive any evidentiary objections to the form or admissibility of such evidence. The respondent must produce admissible evidence in the form required by law in the absence of a stipulation to admissibility by the complainant.

The following are examples of appropriate evidence a respondent may submit to demonstrate his or her rehabilitative efforts and competency:

a. Recent, dated written statements and/or performance evaluations from persons in positions of authority who have on-the-job knowledge of the respondent's current competence in the practice of pharmacy including the period of time and capacity in which the person worked with the respondent. Such reports must be signed under penalty of perjury and will be subject to verification by board staff.
b. Recent, dated letters from counselors regarding the respondent's participation in a rehabilitation or recovery program, which should include at least a description and requirements of the program, a psychologist's diagnosis of the condition and current state of recovery, and the psychologist's basis for determining rehabilitation. Such letters and reports will be subject to verification by board staff.
c. Recent, dated letters describing the respondent's participation in support groups, (e.g., Alcoholics Anonymous, Narcotics Anonymous, professional support groups, etc.). Such letters and reports will be subject to verification by board staff.
d. Recent, dated laboratory analyses or drug screen reports, confirming abstention from drugs and alcohol. Such analyses and reports will be subject to verification by board staff.
e. Recent, dated physical examination or assessment report by a licensed physician, confirming the absence of any physical impairment that would prohibit the respondent from practicing safely. Such assessments and reports will be subject to verification by board staff.
f. Recent, dated letters from probation or parole officers regarding the respondent's participation in and/or compliance with terms and conditions of probation or parole, which should include at least a description of the terms and conditions, and the officer's basis for determining compliance. Such letters and reports will be subject to verification by board staff.

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TERMS OF PROBATION – PHARMACIST/INTERN PHARMACIST

A minimum three-year probation period has been established by the board as appropriate in most cases where probation is imposed. A minimum five-year probation period has been established by the board as appropriate where self-administration or diversion of controlled substances is involved. Terms and conditions are imposed to provide consumer protection and to allow the probationer to demonstrate rehabilitation. A suspension period may also be required as part of the probation order. The board prefers that any stayed order be for revocation rather than for some period of suspension.

Probation conditions are divided into two categories: (1) standard conditions that shall appear in ~~all~~ all probation cases, and (2) optional conditions that depend on the nature and circumstances of a particular case. These conditions may vary depending on the nature of the offense(s).

The board may also impose any other condition appropriate to the case where the condition is not contrary to public policy.

CATEGORIES OF VIOLATIONS AND RECOMMENDED PENALTIES

The California Pharmacy Law ~~specifies the~~identifies offenses for which the board may take disciplinary action against the license. ~~The following are categories of violations used by the board in determining appropriate disciplinary penalties.~~Included among grounds for discipline are violations of the Pharmacy Law itself, violations of regulations promulgated by the board, and violations of other state or federal statutes or regulations.

The following are categories of possible violations used by the board to determine appropriate disciplinary penalties. These categories represent the judgment of the board as to the perceived seriousness of particular offenses.

Under each category, the board has grouped statutes and regulations where violations would typically merit the recommended range of minimum to maximum penalties for that category. These lists are representative, and are not intended to be comprehensive or exclusive. Where a violation not included in these lists is a basis for disciplinary action, the appropriate penalty for that violation may be best derived by comparison to any analogous violation(s) that are included. Where no such analogous violation is listed, the category descriptions may be consulted.

These categories assume a single violation of each listed statute or regulation. For multiple violations, the appropriate penalty shall increase accordingly. Moreover, if an individual has committed violations in more than one category, the minimum and maximum penalties shall be those recommended in the highest category.

The board also has the authority, pursuant to Business and Professions Code section 4301(n), to impose discipline based on disciplinary action taken by another jurisdiction. The discipline imposed by the board will depend on the discipline imposed by the other jurisdiction, the extent of the respondent's compliance with the terms of that discipline, the nature of the conduct for which the discipline was imposed, and other factors set forth in these guidelines.

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CATEGORY I

Minimum: Revocation; Revocation stayed; one year probation. All standard terms and conditions shall be included and optional terms and conditions as appropriate.

Maximum: Revocation

Category I discipline is recommended for:

- violations which are relatively minor but are potentially harmful
- repeated violations of a relatively minor nature:

Violations of the following codes are ~~as follows~~representative of this category:

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BUSINESS AND PROFESSIONS CODE

Article 3. Scope ofPractice and Exemptions

4052.1 Skin Puncture by Pharmacist; Conditions Permitting
4052.5 Pharmacist May Select Different Form of Medication with Same Active Chemical Ingredients; Exceptions
4052.7 Repackage Previously Dispensed Drugs; Requirements
4053 Exemptee Supervisionor of Manufacturers, ~~Wholesalers, and Licensed Laboratories; Veterinary Food-Animal Drug Retailers~~etc.: Requirements
4054 ~~Supplying Dialysis Drugs~~Supply by Manufacturer, etc. of Certain Dialysis Drugs and Devices
4055 Sale of Devices to Licensed Clinics, etc.
4056 ~~Exempt Hospitals~~Purchase of Drugs at Wholesale – Hospital Containing 100 Beds or Less
4057 ~~Exempt Articles~~Exceptions to Application of this Chapter
4058 ~~License to be Displayed~~Display of Original License
4062 ~~Furnishing Drugs during Emergency~~Furnishing Dangerous Drugs During Emergency
4064 Emergency Refills of Prescription Without Prescription Authorization
4065 ~~Administration through Injection Card System~~Injection Card System; Requirements of Administration
4066 ~~Furnishing to Ocean Vessel~~Furnishing Dangerous Drugs to Master or First Officer of Vessel
4068 Dispense Dangerous Drug or Controlled Substance to Emergency Room Patient; Requirements

Article 4. Requirements for Prescription

4070 Reduction of Oral or Electronic Prescription to Writing
4071 ~~Prescriber's Agent Transmitting Prescriptions~~Prescriber May Authorize Agent to Transmit Prescription; Schedule II Excluded
4072 ~~Transmitting Prescriptions from a Health Care Facility~~Oral or Electronic Transmission of Prescription – Health Care Facility
4073 ~~Drug Product Selection~~Substitution of Generic Drug – Requirements and Exceptions
4074 ~~Drug Warnings~~Drug Risk: Informing Patient; Providing Consultation for Discharge Medications
4076 ~~Prescription Label Requirements~~Prescription Container – Requirements for Labeling
4077 ~~Labeling~~Dispensing Dangerous Drug in Incorrectly Labeled Container

Article 5. Authority of Inspectors

4082 ~~Information about Personnel~~Names of Owners, Managers and Employees Open for Inspection

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Article 6. General Requirements

4100 Change of ~~Name or~~ Address or Name – Notification to Board
~~4102 Skin Puncture for Patient Training~~
4103 Blood Pressure ~~Measurement~~– Taking by Pharmacist

Article 7. Pharmacies

4114 Intern Pharmacist ~~Activities~~; Activities Permitted
4119 ~~Emergency Kit for Licensed Health Care Facilities~~Furnish Prescription Drug to Licensed Health Care Facility – Secured
4119.1 Pharmacy May Provide Services to Health Facility
4119.5 ~~Transferring or Repacking Drugs~~Transfer or Repackaging Dangerous Drugs by Pharmacy
4121 ~~Prescription Price Advertising~~Advertisement for Prescription Drug; Requirements; Restrictions
4122 ~~Requests for Prescription Price Information~~Required Notice at Availability of Prescription Price Information, General Product Availability, Pharmacy Services; Providing Drug Price Information; Limitations on Price Information Requests
4123 ~~Pharmacy contracts for Compounding of Parenteral Drugs~~Compounding Drug for Other Pharmacy for Parenteral Therapy; Notice to Board
4124 ~~Contact Lens Dispensing~~Dispensing Replacement Contact Lenses; Requirements; Patient Warnings; Registration with Medical Board; Application of Section to Nonresident Pharmacies

Article 9. Hypodermic Needles and Syringes

4141 ~~License Required~~Furnishing Without License
4142 Prescription Required
4143 Exemption: ~~Wholesale Sales~~ Sale to Other Entity, Physician, etc.
4144 ~~Exemption: Industrial Uses~~Industrial Use Exception
4145 ~~Exemption: Human (Insulin; Adrenaline) or Animal Use~~Exception: Furnishing for Administration of Insulin, Adrenaline, or Specified Animal Uses; Conditions
~~4146 Hypodermic Register~~
4148 Confiscation if Found Outside Licensed Premises
4149 ~~Nonresident~~ Sale by Distributor

Article 10. Pharmacy Corporations

4151 Licensure Requirements ~~for Shareholders, Directors, and Officers~~
4152 Corporate Name Requirements
4153 Shareholder Income While Disqualified
4156 Unprofessional Conduct by Corporation

Article 11. Wholesalers and Manufacturers

4161 ~~Out of State Manufacturer or~~Nonresident Wholesaler; When License Required; Application
4162 ~~Registration – Agent~~Issuance or Renewal of Wholesaler License; Surety Bond
4163 ~~Sales to~~ Unauthorized ~~Persons~~Furnishing by Manufacturer or Wholesaler
4165 Sale or Transfer of Dangerous Drug or Device Into State; Furnishing Records to

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Authorized Officer on Demand: Citation for Non-compliance

4166 ~~Responsibility Until Delivery~~Shipping of Dangerous Drugs or Devices -- Wholesaler or Distributor

4167 ~~Bar on Obtaining More Than Can Be Stored on Licensed Premises~~Wholesaler: Bar on Obtaining Dangerous Drugs or Devices It Cannot Maintain on Licensed Premises

Article 13. Non-Profit or Free Clinics

4180 ~~License Required (Non-Profit, etc Clinics)~~Purchase of Drugs at Wholesale Only with License: Eligible Clinics

4181 License Requirements; Policies and Procedures; Who May Dispense

4182 ~~Application; Consulting Pharmacist~~Duties of Professional Director; Consulting Pharmacist Required

4183 No ~~Medi-Cal~~ Professional Dispensing Fee

4184 ~~No Schedule II~~ Dispensing Schedule II Substance Prohibited

4186 ~~Professional Director~~Automated Drug Delivery Systems

Article 14. Surgical Clinics

4190 Purchase of Drugs at Wholesale: Permitted Uses of Drugs; Required Records and Policies; License Required ~~(Surgical Clinic)~~

4191 ~~License Requirements~~Compliance with Department of Health Services Requirements; Who May Dispense Drugs

4192 Duties of Professional Director; Providing Information to Board

4193 Clinic Not Eligible for Professional ~~No Medi-Cal~~ Dispensing Fee; Ban on Offering Drugs for Sale

4194 ~~No Schedule II~~ Dispensing of Schedule II Substance by Clinic Prohibited; Physician May Dispense; Administration Authorized in Clinic

Article 15. Veterinary Food-Animal Drug Retailers

4196 License Required~~;~~; Temporary License~~; Security~~ on Transfer of Ownership; Persons Authorized in Storage Area

4197 Minimum Standards~~; Waiver~~; Security; Sanitation; Board Regulations; Waivers

4198 Written Policies and Procedures Required:~~;~~ Contents; Training of Personnel; Quality Assurance; Consulting Pharmacist

Article 17. Continuing Education

4231 ~~Renewal~~ Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee

4232 ~~Course~~ Content of Course

Article 18. Poisons

4240 Application of Act

Article 20. Prohibitions and Offenses

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4341 ~~Advertising in Compliance with Sections 651.3~~Advertisement of Prescription Drugs or Devices

4343 ~~Use of Sign with "Pharmacy" or Similar Terms~~Buildings: Prohibition Against Use of Certain Signs Unless Licensed Pharmacy Within

CALIFORNIA CODE OF REGULATIONS, TITLE 16

1704 Change of Address~~address -- reporting a change of address~~

1705 Notification of Bankruptcy, Receivership or Liquidation~~ -- reporting the sale, inventory and location of records of dangerous drugs by a pharmacy, wholesaler or manufacturer in bankruptcy~~

1708.2 Discontinuance of Business~~business -- notification to board of a discontinuance of business and submission of appropriate forms~~

1708.4 Pharmacist h~~H~~andling r~~R~~adioactive d~~D~~rugs~~ -- training of a nuclear pharmacist~~

1708.5 Pharmacy Furnishing Radioactive Drugs~~ -- nuclear pharmacy requirements~~

1709 Names of Owners and Pharmacist in Charge~~pharmacist-in-charge -- required information on a pharmacy permit, reporting PIC and owners on initial and renewal applications, and reporting of corporate officer changes~~

1712 Use of Pharmacist Identifiers

1714 Operational Standards and Security

1715.6 Reporting d~~D~~rug l~~L~~oss~~ -- reporting loss of controlled substances to the Board within thirty (30) day~~

1716 Variation f~~F~~rom p~~P~~rescriptions~~ -- prescription errors, deviation from prescription without consent of prescriber~~

1717 Pharmaceutical p~~P~~ractice~~ -- dispensing in new containers, pharmacist maintain on prescription record: date and initial of pharmacist, brand name of drug or device and indication if generic and manufacturer name, refill information, orally transmitted prescription requirements, depot of a prescription or a medication, prescription transfers, identification of pharmacist responsible for filling a prescription~~

1717.1 Common Electronic Files~~ -- establishing a common electronic file to maintain required dispensing information~~

1717.4 Electronic Transmission of Prescriptions~~ -- transmitting prescriptions by electronic means from prescriber to the pharmacy~~

1718.1 Manufacturer's Expiration Date~~ -- handling of prescription drugs not bearing a manufacturer's expiration date pursuant to federal law~~

1726 ~~Preceptor~~Supervision of Intern Pharmacists

~~1727 Intern Pharmacist~~

1728 ~~Intern Experience --~~ Requirements for ~~Licensure~~Examination

1732.1 Requirements for ~~Recognized~~ Accredited Providers~~ -- requirements to provide continuing education courses as a recognized provider for California pharmacists~~

1732.3 ~~Coursework Approval for Providers~~Requirements for Continuing Education Courses

1732.4 Provider Audit Requirements

1732.5 Renewal Requirements for Pharmacist

1744 Drug w~~W~~arnings~~ -- oral or written warnings when a drug should not be taken with alcohol or when a person should not drive~~

1746 Emergency Contraception

~~1751 to 1751.09 and 1751.11 to~~

Deletions to the regulatory text are indicated by double strike-through, thus: ~~deleted language~~. Additions to the regulatory text are indicated by a double underline, thus: added language

~~1751.12 Compounding Area for Parenteral Solutions—parenteral therapy requirements for pharmacists and pharmacies~~
1751 Sterile Injectable Compounding Area
1751.01 Facility and Equipment Standards for Sterile Injectable Compounding from Non-Sterile Ingredients
1751.02 Policies and Procedures
1751.1 Laminar Flow Biological Safety Cabinet
1751.2 Labeling Requirements
1751.3 Recordkeeping Requirements
1751.4 Attire
1751.5 Training of Staff, Patient, and Caregiver
1751.6 Disposal of Waste Material
1751.7 Quality Assurance and Process Evaluation
1751.9 Reference Materials
1751.11 Furnishing to Home Health Agencies and Licensed Hospices
1751.12 Obligations of a Pharmacy Furnishing Portable Containers
1771 Posting ~~n~~Notice of ~~s~~Suspension—~~suspended pharmacy must post a notice of suspension~~
1772 Disciplinary ~~c~~Conditions of ~~s~~Suspension—~~suspended pharmacist shall not enter a pharmacy prescription area or perform pharmacy related duties~~
1780 Minimum ~~s~~Standards for ~~w~~Wholesalers
1780.1 Minimum Standards for Veterinary Food-Animal Drug Retailers
1781 Exemption ~~c~~Certificate—~~exemptee must be present in a manufacturer's or wholesaler's licensed premises~~
1786 Exemptions—~~return of exemption certificate to board upon termination of employment~~
1787 Authorization to Distribute Hemodialysis Drugs and Devices
1790 Assembling and Packaging
1791 Labeling
1792 Receipt ~~of~~ for Shipment

HEALTH AND SAFETY CODE~~, TITLE 22~~

11100 Report of Certain Chemical: Chemicals Included; Exclusions; Penalties~~controlled substance transaction—reporting sales of restricted chemicals to Department of Justice~~
11100.1 Report of Chemicals Received ~~controlled substances received~~ from ~~o~~Outside ~~s~~State; Penalties—~~reporting Purchases of restricted chemicals from outside California~~
~~11124 Inventory of Controlled Substances~~
11151 Limitation on Filling Prescriptions From Medical Students ~~Issued By Unlicensed Person Lawfully Practicing Medicine~~
11158 Prescription ~~r~~Required for Schedule ~~I,~~ II, III, ~~or~~ IV, or V ~~c~~Controlled ~~s~~Substance; Exception for Limited Dispensing, Administrations—~~prescriptions for controlled substances must comply with requirements prior to dispensing~~
11159 Chart Order Exemption for ~~p~~Patient in ~~c~~County or ~~l~~Licensed ~~h~~Hospital; Maintaining Record for Seven Years—~~controlled substance orders in hospitals~~
11159.1 Chart Order Exemption for Clinic ~~Records~~Patient; Maintaining Record for Seven Years
11159.2 Exception to Triplicate Prescription Requirement~~Terminally Ill Exception~~

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11167 Emergency ~~d~~Dispensing of Schedule II ~~s~~Substance; Circumstances and Requirements—~~emergency oral Schedule II prescriptions; must receive a triplicate within seventy-two (72) hours~~
11167.5 ~~Emergency o~~Oral or Electronic ~~p~~Prescriptions for Scheduled II Controlled Substances for Specified ~~i~~In-patients, Residents, and Home Hospice Patients; Requirements—~~oral orders for Schedule II drugs in a skilled nursing facility, intermediate care facility, or a home health care agency providing hospice care; pharmacy to obtain special triplicates from Dept. of Justice; facility must forward all signed order to the pharmacy~~
11171 Prescribing, etc.—~~administering, or furnishing c~~Controlled ~~s~~Substance Only as Authorized—~~furnishing controlled substances must be consistent with law~~
11172 Antedating or ~~p~~Postdating ~~p~~Prescription Prohibited
11175 Prohibition on Obtaining ~~and or p~~Possession~~ng~~ ~~n~~Nonconforming ~~p~~Prescription; Prohibition on ~~o~~Obtaining ~~c~~Controlled ~~s~~Substance by ~~n~~Nonconforming ~~p~~Prescription
11180 Prohibition on Controlled ~~s~~Substance ~~o~~Obtained or ~~p~~Possessed by ~~n~~Nonconforming ~~p~~Prescription —~~possession of a controlled substance obtained from noncomplying prescriptions~~
11200 Restrictions on ~~d~~Dispensing or ~~r~~Refilling; Refill of Schedule II Prescription Barred—~~refill restrictions of controlled substances~~
11201 Emergency Refill ~~by Pharmacist~~of Schedule III, IV, or V Prescription; Circumstances; Requirements
11205 Maintenance and ~~r~~Retention of Records in Separate ~~f~~File—~~separate prescription file for Schedule II prescriptions~~
11206 Required ~~information~~information on Prescription—~~information required on a prescription for controlled substances~~
11209 Delivery and Receiving Requirements for Schedule II, III, and IV ~~of Controlled~~ Substances; Violation
11210 Issuing Prescription; By Whom; For What Purpose; Quantity to Be Prescribed ~~under authorized project - a prescriber may not prescribe controlled substances to treat addiction~~
11250 Authorized Retail Sale by Pharmacists to Physicians, etc.; Required Order Form
11251 Authorized Wholesale Sale by Pharmacists
11252 Preservation of ~~f~~Federally ~~r~~Required ~~f~~Forms—~~a wholesaler or manufacturer must maintain records of sales~~
11253 Duration of ~~r~~Retention
11255 Actions ~~c~~Constituting ~~s~~Sale—~~orders for future delivery constitutes a sale of a controlled substance~~
11256 Required Report of Order ~~b~~By or Sale to Out-of-State Wholesaler or Manufacturer
111225 to 111655 Adulterated or Misbranded Drugs or Devices

CODE OF FEDERAL REGULATIONS, TITLE 21

~~1.~~1301.11 Persons ~~R~~required to ~~R~~register.
~~2.~~1301.12 Separate ~~R~~registrations for ~~S~~separate ~~L~~locations.
1301.71 Security requirements~~,~~ generally.
1301.72 Physical security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; storage areas.
1301.73 Physical security controls for non-practitioners; compounders for narcotic treatment programs; manufacturing and compounding areas.

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1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.
~~1.~~1301.75 Physical security controls for practitioners.
~~2.~~1301.76 Other ~~S~~security ~~C~~controls for ~~P~~practitioners.
1301.90 Employee screening procedures.
1301.91 Employee responsibility to report drug diversion.
1301.92 Illicit activities by employees.
1302.03 Symbol required; exceptions.
1302.04 Location and size of symbol on label and labeling.
1302.05 Effective ~~D~~dates of ~~L~~labeling ~~R~~requirements.
1302.06 Sealing of controlled substances.
1302.07 Labeling and packaging requirements for imported and exported substances.
1304.11 Inventory requirements.
~~1304.18~~ 1304.21 ~~—~~Inventories of importers and exporters
~~1305.03 to~~
~~1305.06 and~~
~~1305.08 to~~
~~1305.12 and~~
~~1305.14 to~~
~~1305.16 Distributions requiring order forms; persons entitled to obtain and execute order forms; procedure for obtaining order forms; procedure for executing order forms; persons entitled to fill order forms; procedure for filling order forms; procedure for endorsing order forms; unaccepted and defective order forms; lost and stolen order forms; return of unused order forms~~
1304.31 Reports from manufacturers importing narcotic raw materials.
1304.32 Reports of manufacturers importing coca leaves.
1304.33 Reports to ARCOS.
1305.03 Distributions requiring a Form 222 or a digitally signed electronic order.
1305.04 Persons entitled to order Schedule I and II controlled substances.
1305.05 Power of attorney.
1305.06 Persons entitled to fill orders for Schedule I and II controlled substances.
1305.11 Procedure for obtaining DEA Forms 222.
1305.12 Procedure for executing DEA Forms 222.
1305.14 Procedure for endorsing DEA Forms 222.
1305.15 Unaccepted and defective DEA Forms 222.
1305.16 Lost and stolen DEA Forms 222.
1306.03 Persons entitled to issue prescriptions.
1306.05 Manner of issuance of prescriptions.
1306.14 Labeling of substances and filling of prescriptions. ~~—Schedule II.~~
1306.24 Labeling of substances and filing of prescriptions. ~~—Schedule III and IV~~
~~1.~~1306.25 Transfer between pharmacies of prescription information for ~~of~~ Schedules III, IV, and V controlled substances for refill purposes. ~~Prescriptions~~
1306.26 Dispensing ~~W~~without a ~~P~~prescription.
1307.11 Distribution by dispenser to another practitioner or reverse distributor.~~—~~
1307.12 Distribution to supplier or ~~M~~manufacture. ~~and distribution of narcotic solutions and compounds by a pharmacist~~
1307.13 Incidental manufacture of controlled substances. ~~Distribution to supplier~~
1307.21 Procedure for disposaling of controlled substances.
1700.1 to
1707.15 Child-resistant containers.

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~~MISCELLANEOUS – HEALTH AND SAFETY CODE, TITLE 22~~

~~111225 to~~
~~111655 Adulterated or misbranded drugs or devices~~

~~MISCELLANEOUS – FEDERAL REGULATIONS~~

~~16 CFR 1700.1 to~~
~~1707.15 Child-resistant containers~~

CATEGORY II

Minimum: Revocation; Revocation stayed, three years probation (five years probation where self-administration or diversion of controlled substances is involved). All standard terms and conditions shall be included and optional terms and conditions as appropriate.

Maximum: Revocation

Category II discipline is recommended for:
- violations with a serious potential for harm
- violations which involve greater disregard for pharmacy law and public safety
- violations which reflect on ethics, care exercised or competence or a criminal conviction not involving dangerous drugs or controlled substances or involving possession or use of dangerous drugs or controlled substances.

Violations of the following codes are ~~as follows~~representative of this category:

BUSINESS AND PROFESSIONS CODE

650 Rebates or Discounts for Referral Prohibited
650.1 Lease Prohibition – Hospitals or Prescribers
651 Professional Advertising Requirements

Article 3. Scope of Practice and Exemptions

4051(b) Conduct Authorized by Pharmacist ~~from Outside Pharmacy~~
4052 ~~conduct Authorized by Pharmacist~~Furnishing to Prescriber; Permissible Procedures by Pharmacist in Health Care Facility or Clinic or for Other Health Care Provider
4060 ~~Possession of~~ Controlled Substance – Prescription Required; Exceptions
4061 Distribution of Drug as Sample; Written Request Required ~~Drugs~~
4063 Refills of Prescription for Dangerous Drug or Device; Prescriber Authorization
4067 ~~Prescription Dispensing over the~~ Internet; Dispensing Dangerous Drugs or Devices without Prescription
~~17934~~4075 Proof of Identity Required – Oral or Electronic Prescription ~~of Recipient for~~

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Article 6. General Requirements

Article 7. Pharmacies

Article 9. Hypodermic Needle and Syringes

Article 11. Wholesalers and Manufacturers

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Article 13. Non-Profit of Free Clinics

Article 14. Surgical Clinics

Article 19. Disciplinary Proceedings

Article 20. Prohibitions and Offenses

Article 22. Unfair Trade Practices

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Exceptions
4381 Violation of Section 4380 as Unfair Competition; Right of Private Action to Enforce
4382 ~~Authority of Board to Audit for Compliance~~Board May Audit Sales to Walk-in Customers

CALIFORNIA CODE OF REGULATIONS, TITLE 16

1707.1 Duty to ~~m~~Maintain ~~m~~Medication ~~p~~Profiles (~~p~~Patient ~~m~~Medication ~~r~~Records)~~—requirements for maintenance of patient medication profiles~~
1707.2 Notice to ~~c~~Consumers and ~~d~~Duty to ~~c~~Consult~~—requirements of pharmacist to consult; posting of notice to consumers~~
1707.3 ~~Reviewing the patient profile prior to consultation~~Duty to Review Drug Therapy and Patient Medication Record Prior to Delivery
1709.1 Designation of ~~p~~Pharmacist in ~~c~~Charge
1714.1 Pharmacy Operations ~~d~~During ~~-~~the Temporary Absence of a Pharmacist
1715 Self-Assessment of a Pharmacy by the Pharmacist-in-Charge
1715.5 ~~Transmitting Schedule II Prescription Information to CURES~~Implementation of Electronic Monitoring of Schedule II Prescriptions
1716.1 Compounding Unapproved ~~d~~Drugs for ~~p~~Prescriber ~~o~~Office ~~u~~Use
1716.2 Record ~~r~~Requirements~~, when c~~Compounding for ~~f~~Future ~~f~~Furnishing
~~1717.2 Notice of Electronic Prescription Files~~
1717.3 Preprinted, ~~m~~Multiple ~~c~~Check-off ~~p~~Prescription ~~b~~Blanks
1723.1 Confidentiality of Examination Questions
1745 Partial ~~f~~Filling of Schedule II ~~p~~Prescriptions
1751.10 Furnishing to ~~p~~Parenteral ~~p~~Patient at ~~h~~Home~~—carrying and furnishing dangerous drugs to parenteral patients~~
1761(a) Erroneous or Uncertain Prescriptions~~—~~
1764 Unauthorized ~~d~~Disclosure of ~~p~~Prescriptions~~—revealing the contents of a prescription to unauthorized persons~~
1765 Commissions, ~~g~~Gratuities, and ~~r~~Rebates~~—commission, gratuity or rebate to a health care facility~~
1766 False or ~~m~~Misleading ~~a~~Advertising
1775.3 Compliance with Orders of Abatement
1782 Reporting Sales of Drugs Subject to Abuse
1783 Manufacturer or Wholesaler Furnishing Drugs or Devices
~~1793.1 to~~
~~1793.7 Ancillary personnel - pharmacy technician requirements and tasks~~
1793.1 Duties of a Pharmacist
1793.2 Duties of a Pharmacy Technician
1793.3 Other Non-Licensed Pharmacy Personnel
1793.7 Requirements for Pharmacies Employing Pharmacy Technicians
1793.8 Technicians in Hospitals with Clinical Pharmacy Programs

HEALTH AND SAFETY CODE~~, TITLE 22~~

11103 Report of ~~t~~Theft, ~~l~~Loss, or ~~s~~Shipping ~~d~~Discrepancy~~—reporting losses of restricted chemicals to Department of Justice~~
~~11123 Warehouseman License~~
~~11124 Warehouse Inventory~~

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~~11125 Warehouseman Bond~~
~~11128 Nontransferability of Warehouse License~~
~~11129 Discipline or Denial of Warehouse License~~
~~11130 Disciplinary Grounds for Warehouse License~~
~~11131 Disciplinary Grounds for Warehouse License~~
11150 ~~Issuing Controlled Substance~~ Persons Authorized to Write or Issue a Prescription
11152 Nonconforming ~~p~~Prescriptions Prohibited~~—filling a prescription that does not conform to the requirements of the code~~
11154 Prescription, etc, Must Be for Treatment; Knowing~~Issuing Prescriptions;~~ Solicitingation of Unlawful Prescription, etc.
11156 Prescribing, etc.~~Administering or dispensing~~ ~~c~~Controlled ~~s~~Substances to ~~a~~Addict Only as Authorized~~—prohibition on administering or dispensing a controlled substance to an addict or a habitual user~~
11164 ~~Completion of~~ ~~p~~Prescriptions for Schedule II, III, IV and~~-~~ V ~~c~~Controlled ~~s~~Substances: Form and Content; Record of Practitioner Dispensing Schedule II Controlled Substances~~—prescription requirements for controlled substances~~
11166 Time Limit ~~F~~for Filling Schedule II Prescriptions; Knowingly Filling Mutilated, Forged, or Altered Prescriptions Prohibited
11170 Prohibition on Prescribing, etc. ~~c~~Controlled ~~s~~Substance for ~~s~~Self ~~use—prohibition on prescribing, administering or furnishing controlled substance to self~~
11179 Retention of Controlled Substance Prescription~~period—prescription file to be maintained for three (3) years~~
11207 ~~Filling prescription o~~Only ~~by p~~Pharmacist or ~~i~~Intern Authorized to Fill Prescription~~pharmacist—dispensing, compounding, filling by pharmacist or intern pharmacist only~~
11209 Delivery and Receiving Requirements for Schedule II, III, ~~&~~and IV Substances; Violation
11350 Possession of ~~s~~Specified ~~c~~Controlled ~~s~~Substance~~—illegal possession of a narcotic~~
11377 Unlawful ~~p~~Possession of ~~s~~Specified ~~s~~Substance~~—illegal possession of a non-narcotic controlled substance~~
11165(d) CURES Transmission
150204 Surplus Medication Collection and Distribution Program

CODE OF FEDERAL REGULATIONS, TITLE 21

1304.03 Persons required to keep records and file reports.
1304.04 Maintenance of records and inventories.
1304.11 ~~General~~ Inventory requirements ~~for inventories~~.
1304.21 General requirements for continuing records.
1304.22 Records for manufacturers.
1305.07 ~~Power of attorney~~Special procedure for filling certain orders.
1305.13 ~~Preservation of order forms~~Procedure for filling DEA Forms 222.
1306.04 Purpose of issue of prescription.
1306.06 Persons entitled to fill prescriptions.
1306.07 Administering or dispensing of narcotic drugs.
1306.11 Requirement of ~~Schedule II P~~prescriptions.
1306.12 Refilling prescriptions~~—Schedule II~~.
1306.13 Partial filling of prescriptions~~—Schedule II~~.
1306.21 Requirement of prescription~~—Schedule III and IV~~.
1306.22 Refilling of prescriptions~~—Schedule III and IV~~.

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1306.23 Partial filling of prescriptions—Schedule III and IV.

CATEGORY III

Minimum: Revocation; Revocation stayed, 90 days actual suspension, three to five years probation (five years probation where self-administration or diversion of controlled substances is involved). All standard terms and conditions and optional terms and conditions as appropriate.

Maximum: Revocation

Category III discipline is recommended for:

- most criminal convictions involving dangerous drugs or controlled substances
- knowing or willfully violating laws or regulations pertaining to dispensing or distributing dangerous drugs or controlled substances
- fraudulent acts committed in connection with the licensee's practice
- drug shortages
- violation of a licensee's corresponding responsibility.

Violations of the following codes are as followsrepresentative of this category:

BUSINESS AND PROFESSIONS CODE

Article 3. Scope of Practice and Exemptions

4034 Pedigree
4051(a) Conduct Limited To Pharmacist
4059 Furnishing Dangerous Drugs or Devices Prohibited Without Prescription; Exceptions
4059.5 Who May Ordering Dangerous Drugs or Devices; Exceptions

Article 5. Authority of Inspectors

4080 Stock of Dangerous Drugs and Devices Kept Open for Inspection
4081 Records of Acquisition and Dispensing; InspectionDangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory
4085(a) Unlawful to Remove, Sell, Dispose of Embargoed Dangerous Drug or Dangerous Device

Article 6. General Requirements

4105 Retaining Records of Dangerous Drugs and Devices on Licensed Premises; Temporary Removal; Waivers; Access to Electronically Maintained Records

Article 7. Pharmacies

4110 Requirement of License; Temporary LicensesLicensed Required; Temporary Permit Upon Transfer of Ownership
4111 Ownership by Prescribers ProhibitedRestrictions on Prescriber Ownership

Article 11. Wholesalers and Manufacturers

4169(a)(2) to
4169(a)(5) Prohibited Acts

Article 15. Veterinary Food-Animal Retailers

4199 Labeling, Recordkeeping Requirements; Maintaining Prescription Records

Article 19. DisciplinaryProceedings

4301 Unprofessional Conduct - Ssubsections (i) and (k) and (o)
4307 Prohibition Against Association with a Licenseof Association of Individual with Entity License by Board; Length of Prohibition; Individuals Covered; Imposition of Prohibition Through Administrative Act Proceeding
4308 Notification of Licensee Person is Prohibited from Association; ReplacementProhibited Association; Notification of Affected Licensees Known to Board

Article 20. Prohibitions and Offenses

4322 False Representation to Obtain LicensureMisdemeanor or Infraction: False Representations to Secure License for Self or Others; False Representation of Licensure; Penalties
4323 False Representation by Telephone or Electronic Transmission to Obtain a DrugMisdemeanor: False Representation of Self as Physician, Agent of Physician, etc. to Obtain Drug
4324 Forgery or AlterationFelony or Misdemeanor: Forgery of Prescription; Possession of Drugs Obtained Through Forged Prescription
4325 Producing Prescription Blanks Without AuthorizationMisdemeanor: Manufacture, Possession, etc. of False Prescription Blank
4327 Use of Alcohol or Drugs while on DutyMisdemeanor: Sale, Dispensing, or Compounding While Under the Influence of Drugs or Alcoholic Beverages
4329 Nonpharmacist Taking ChargeMisdemeanor: Non-pharmacist Acting as Manager, Compounding, Dispensing or Furnishing Drugs
4332 Failure or Refusal to Produce or Provide RecordsMisdemeanor: Failure or Refusal to Maintain or Produce Required Drug or Device Records; Willful Production of False Records
43354335 Failure to Arrange for Transfer of Stock after ClosureVoided License: Knowing Failure to Arrange for Disposition of Stock as Misdemeanor
43364336 Use of Minor as Agent to Violate Pharmacy LawFelony: Knowing or Willful Use of Minor to Violate Specified Sections of Pharmacy Law: Exception for Pharmacist Furnishing Pursuant to a Prescription

Article 22. Unfair Trade Practices

4380 Resale of Preferentially Priced Drugs: Prohibition; Exceptions

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CALIFORNIA CODE OF REGULATIONS, TITLE 16

1707	Waiver Requirements for Off-Site Storage of Records
1718	Current iInventory dDefined~~—audit accountability of dangerous drugs~~
1761(b)	~~Controlled substance prescription—professional judgment~~Erroneous or Uncertain Prescriptions
~~1771 to~~	
~~1774~~	~~Disciplinary conditions of suspension and probation~~
1771	Posting of Notice of Suspension
1772	Disciplinary Condition of Suspension
1773	Disciplinary Conditions of Probation of Pharmacist
1774	Disciplinary Conditions of Probation of Permit

HEALTH AND SAFETY CODE, ~~TITLE 22~~

11104	Providing Chemical for Illicit Manufacturing; Evasion of Reporting Requirements; Penalties~~controlled substances for manufacturing~~
11105	False sStatement in rReport
~~11122~~	~~Storage of controlled substances~~
11150	Persons aAuthorized to wWrite or iIssue a pPrescription
11153	Responsibility for Legitimacy of ~~controlled substance~~ pPrescription; ~~–~~ cCorresponding rResponsibility of ~~a~~ pPharmacist; Knowing Violation
11153.5	Wholesaler or Manufacturer Furnishing ~~a~~ cControlled sSubstance ~~for~~ oOther tThan for ~~a~~ iLegitimate mMedical pPurpose; Knowing Violation; Factors in Assessing Legitimacy~~—corresponding responsibility of a wholesaler or manufacturer~~
11157	No False or fFictitious pPrescriptions~~—issuing a false or fictitious prescription~~
11162.5	Counterfeiting or pPossession of cCounterfeit Triplicate pPrescription bBlank; Penalty
11173	Fraud, dDeceit, ~~m~~Misrepresentation or fFalse sStatement; False Representation; False Label~~—obtaining controlled Substances by fraud or deceit~~
11174	Prohibition on Providing False ~~n~~Name or ~~a~~Address in Connection with Prescription, ~~etc.—false name or address on prescription~~
11351	Possession or pPurchase for sSale of sSpecified cControlled sSubstance~~—illegal possession for sale of a narcotic~~
11368	Forged or aAltered pPrescriptions~~forging a narcotic prescription~~
11375	Possession for sSale or sSelling sSpecified sSubstance
11378	Possession for ~~s~~Sale~~illegal possession for sale of a nonnarcotic~~
11550	Useing or bBeing uUnder ~~the~~ iInfluence of cControlled sSubstance
11167.5	Pharmacy Generated Prescription for Schedule II Controlled Substances in a Skilled Nursing Facility
111295	Manufacturing, Selling, or Offering for Sale an Adulterated Drug or Device
111300	Unlawful to Adulterate a Drug
111305	Unlawful to Receive in Commerce an Adulterated Drug
111440	Unlawful Manufacturer, Selling a Misbranded Drug
111445	Unlawful for a Person to Misbrand
111450	Unlawful to Receive into Commerce a Drug that is Misbranded

CATEGORY IV

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Penalty: Revocation

Revocation is recommended for violations of the Uniform Controlled Substance Act (Heath and Safety Code 11000 et seq.) ~~when~~involving:

- ~~[illegible]~~ possession for sale
- ~~[illegible]~~ transportation
- ~~[illegible]~~ importation
- ~~[illegible]~~ sale
- ~~[illegible]~~ use of a minor for the unlawful sale of controlled substances

Revocation is also recommended when:

- ~~[illegible]~~ a respondent fails to file a notice of defense or to appear at a disciplinary hearing where the board has requested revocation in the accusation
- ~~[illegible]~~ a respondent violates the terms and conditions of probation from a previous disciplinary order
- ~~[illegible]~~ prior discipline has been imposed, as progressive discipline unless the respondent can demonstrate satisfactory evidence of rehabilitation.

Violations of the following codes are ~~as follows~~representative of this category:

HEALTH AND SAFETY CODE, ~~TITLE 22~~

11352	Importing, sSelling, fFurnishing cControlled sSubstance~~—illegal sale of a narcotic~~
11353	Adult iInducing ~~m~~Minor to vViolate ~~controlled substances~~ pProvisions
11379	Transporting, iImporting, sSelling cControlled sSubstances~~—illegal sale of a non-narcotic~~
11380	Adult ~~u~~Using, sSoliciting or iIntimidating ~~m~~Minor for vViolation~~—violation of non-narcotic provisions or the use of a minor~~

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MODEL DISCIPLINARY LANGUAGE – PHARMACIST/INTERN PHARMACIST

The following standardized language shall be used in every decision where the order or condition is imposed.

Revocation ~~– Single Cause~~

License number _____, issued to respondent _____ is revoked.

Respondent shall relinquish his or her wall license and pocket renewal license to the board within 10 days of the effective date of this decision. Respondent may not reapply or petition the board for reinstatement of his or her revoked license for three years from the effective date of this decision.

Respondent shall pay to the board its costs of investigation and prosecution in the amount of $_____ within fifteen (15) days of the effective date of this decision.

Option: ~~Upon~~ As a condition precedent to reinstatement of his or her revoked license, respondent shall reimburse the board for its costs of investigation and prosecution in the amount of $_____. Said amount shall be paid in full prior to the reapplication or reinstatement of his or her license unless otherwise ordered by the board. ~~If respondent fails to pay the amount specified, his or her license shall remain revoked.~~

~~**Revocation – Multiple Causes**~~

~~License number _____, issue to respondent _____ is revoked pursuant to Determination of Issues _____, separately and together.~~

~~Respondent shall relinquish his or her wall license and pocket renewal license to the board within 10 days of the effective date of this decision. Respondent may not petition the board for reinstatement of his or her revoked license for three years from the effective date of this decision. Respondent shall pay to the board its costs of investigation and prosecution in the amount of $_____ within 15 days of the effective date of this decision.~~

~~**Option:** Upon reinstatement of his or her revoked license, respondent shall reimburse the board for its costs of investigation and prosecution in the amount of $_____. Said amount shall be paid in full prior to the reinstatement of his or her license. If respondent fails to pay the amount specified, his or her license shall remain revoked.~~

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Suspension ~~– Single Cause~~

~~License number _____, issued to respondent _____ is suspended for a period of _____.~~ As part of probation, respondent is suspended from the practice of pharmacy for _____ beginning the effective date of this decision.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances.

Respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

~~**Suspension – Multiple Causes**~~

~~License number _____, issued to respondent is suspended for a period of _____ pursuant to Determination of Issues _____, separately and together. All suspensions shall run concurrently.~~

~~Respondent is suspended from the practice of pharmacy for _____ beginning the effective date of this decision.~~

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Standard Stay/Probation Order

License number _____, issued to respondent is revoked ~~_____~~; however, the revocation ~~_____~~ is stayed and respondent is placed on probation for _____ years upon the following terms and conditions:

Issuance of Probationary License (In cases where a Statement of Issues has been filed.)

~~The application for licensure of respondent is hereby granted, on the following terms and conditions:~~

~~1. That, respondent first meet all statutory and regulatory requirements for the issuance of a license to _____.~~

~~2. That, following the satisfaction of #1, respondent's license be issued and immediately revoked, the order of revocation being stayed and respondent placed on probation for a period of _____ years on the following terms and conditions:~~

Upon satisfaction of all statutory and regulatory requirements for issuance of a license, a license shall be issued to respondent and immediately revoked; the order of revocation is stayed and respondent is placed on probation for _____ years upon the following terms and conditions:

Surrender

Respondent surrenders license number _____ as of the effective date of this decision. Respondent shall relinquish his or her wall license and pocket renewal license to the board within ten (10) days of the effective date of this decision.

The surrender of respondent's license and the acceptance of the surrendered license by the board shall constitute the imposition of discipline against respondent. This decision constitutes a record of discipline and shall become a part of respondent's license history with the board.

Respondent understands and agrees that if he or she ever files an application for licensure or a petition for reinstatement in the State of California, the board shall treat it as a new application for licensure.

Respondent may not ~~re~~apply for any license, permit, or registration from the board for three years from the effective date of this decision. Respondent stipulates that should he or she apply for any license from the board on or after the effective date of this decision, all allegations set forth in the [accusation or petition to revoke probation] shall be deemed to be true, correct and admitted by respondent when the board determines whether to grant or deny the application. Respondent shall satisfy all requirements applicable to that license as of the date the application is submitted to the board, including, but not limited to taking and passing the California Pharmacist Licensure Examination prior to the issuance of a new license. Respondent is ~~obligated~~ required to report this surrender as disciplinary action.

Respondent further stipulates that he or she shall reimburse the board for its costs of investigation and prosecution in the amount of $_____ within _____ days of the effective date of this decision.

Option: Respondent stipulates that should he or she apply for any license from the board on or after the effective date of this decision the investigation and prosecution costs in the amount of $_____ shall be paid to the board prior to issuance of the new license.

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Public Reprimand

It is hereby ordered that a public reprimand be issued against licensee, _____. Respondent is required to report this reprimand as a disciplinary action.

Adoption of Stipulation

It is understood by respondent that, in deciding whether to adopt this stipulation, the board may receive oral and written communication from its staff and the ~~Attorney General's Office~~ of the Attorney General. Communications pursuant to this paragraph shall not disqualify the board or other persons from future participation in this or any other matter affecting respondent. In the event this settlement is not adopted by the board, the stipulation will not become effective and may not be used for any purpose, except this paragraph, which shall remain in effect.

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STANDARD CONDITIONS - To be included in all probation decisions/orders.

~~Term Number: (Numbers reflect actual term and condition numbers as listed beginning with page _____.)~~

1. Obey aAll Laws
2. Reporting to the Board
3. Interview with the Board
4. Cooperation with Board Staff
5. Continuing Education
6. Notice to Employers
7. No ~~Preceptorships,~~ Supervision of Interns, ~~Being~~Serving as Pharmacist-In-Charge (PIC), or Serving as a Consultant
8. Reimbursement of Board Costs
9. Probation Monitoring Costs
10. Status of License
11. License Surrender While on Probation/Suspension
12. Notification of a Change in Name, Residence Address, ~~Employment~~/Mailing Address or Employment ~~Change~~
13. Tolling of Probation
14. Violation of Probation
15. Completion of Probation

OPTIONAL CONDITIONS

~~Term Number: (Numbers reflect actual term and condition numbers as listed beginning with page _____.)~~

~~1. Actual Suspension~~
~~2.~~16. Restricted Practice
~~3.~~17. Pharmacist Examination
~~4.~~18. Mental Health Examination
~~5.~~19. Psychotherapy
~~6.~~20. Medical Evaluation
~~7.~~21. ~~Rehabilitation Program~~Pharmacists Recovery Program (PRP)
~~8.~~22. Random Drug Screening
~~9.~~23. Abstain from Drugs and Alcohol Use
24. Prescription Coordination and Monitoring of Prescription Use
~~10.~~25. Community Service Program
~~11.~~26. Restitution
~~12.~~27. Remedial Education
28. Pharmacy Self-Assessment Mechanism (PSAM)
~~13.~~29. ~~Pharmacy~~ Intern Pharmacist Experience
~~14.~~30. Supervised Practice
~~15.~~31. No Supervision of Ancillary Personnel
~~16.~~32. No Ownership of Licensed Premises
~~17.~~33. Separate File of Records
~~18.~~34. Report of Controlled Substances
~~19.~~35. No Access to Controlled Substances
~~20.~~36. Criminal Probation/Parole Reports
~~21.~~37. Consultant for Owner or Pharmacist-In-Charge

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~~22.~~38. Tolling of Suspension
39. Surrender of DEA Permit
40. Ethics Course

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STANDARD CONDITIONS: TO BE INCLUDED IN ALL PROBATIONS

~~1.~~1. Obey All Laws

Respondent shall obey all state and federal laws and regulations ~~substantially related to or governing the practice of pharmacy~~.

Respondent shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- discipline, citation, or other administrative action filed by any state ~~and~~ or federal agency which involves respondent's _____ license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, ~~or distribution~~ distributing, ~~or~~ billing, or charging for ~~of~~ any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

~~2.~~2. Reporting to the Board

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, ~~R~~respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, ~~i~~If the final probation report ~~is not~~ is not made as directed, probation shall be automatically extended ~~automatically~~ until such time as the final report is made and accepted by the board.

~~3.~~3. Interview with the Board

Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, at such ~~upon request at various~~ intervals and ~~at a~~ locations as are ~~to be~~ determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

~~4.~~4. Cooperation~~e~~ with Board Staff

Respondent shall cooperate with the board's inspectional program and ~~in~~ with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his or her probation. Failure to ~~comply~~ cooperate shall be considered a violation of probation.

~~5.~~5. Continuing Education

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~~——~~Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

6. Notice to Employers

During the period of probation, ~~R~~respondent shall notify all present and prospective employers of the decision in case number _____ and the terms, conditions and restrictions imposed on respondent by the decision, as follows:~~.~~

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause his or her direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and/~~or~~ owner to report to the board in writing acknowledging that the listed individual(s) has/have ~~employer has~~ read the decision in case number _____, and terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

If respondent works for or is employed by or through a pharmacy employment service, respondent must notify ~~the~~ his or her direct supervisor, pharmacist-in-charge, and/~~or~~ owner at every ~~pharmacy~~ entity licensed by the board of the ~~and~~ terms and conditions of the decision in case number _____ in advance of the respondent commencing work at each ~~pharmacy~~ licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy employment service, respondent shall cause his or her direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that he or she has read the decision in case number _____ and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgments to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision shall include any full-time, part-time, temporary, relief or pharmacy management service as a pharmacist or any position for which a pharmacist license is a requirement or criterion for employment, whether the respondent is ~~considered~~ an employee, ~~or~~ independent contractor or volunteer.

~~7.~~7. No ~~Preceptorships,~~ Supervision of Interns, ~~Being~~ Serving as Pharmacist-in-Charge (PIC), Serving as Designated Representative-in-Charge, or Serving as a Consultant

During the period of probation, ~~R~~respondent shall not supervise any intern pharmacist, ~~or perform any of the duties of a preceptor, nor shall respondent~~ be the pharmacist-in-charge or designated representative-in-charge of any entity licensed by the board nor serve as a consultant unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

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~~8.~~8. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, ~~R~~respondent shall pay to the board its costs of investigation and prosecution in the amount of $_____. Respondent shall make said payments as follows: _____.

There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondent shall not relieve respondent of his or her responsibility to reimburse the board its costs of investigation and prosecution.

~~Option: If respondent fails to make any payment by the directed deadline(s), the stay shall terminate and the license shall be revoked without further notice or opportunity to be heard.~~

~~9.~~9. Probation Monitoring Costs

Respondent shall pay ~~the~~ any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board ~~at the end of each year of probation~~ on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

~~10.~~10. Status of License

Respondent shall, at all times while on probation, maintain an active, current license with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.

If respondent's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication, respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

11. ~~License Surrender w~~While on Probation/Suspension

Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his or her license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the board.

Upon acceptance of the surrender, respondent shall relinquish his or her pocket and wall license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent may not reapply for any license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board, including any outstanding costs.

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~~11~~12. Notification of a Change in Name, Residence Address, ~~Employment~~/Mailing Address or Employment~~Change~~

Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, ~~and/or~~ the address of the new employer, the name of the supervisor ~~or~~ and owner, and the work schedule if known. Respondent shall further notify the board in writing within ten (10) days of a change in name, residence address, mailing address, or phone number.

Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

~~13.~~13. Tolling of Probation

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a pharmacist in California for a minimum of _____ hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation.

Should respondent, regardless of residency, for any reason (including vacation) cease practicing ~~pharmacy~~ as a pharmacist for a minimum of _____ hours per calendar month in California, respondent must notify the board in writing within ten (10) days of the cessation of ~~the~~ practice ~~of pharmacy or~~, and must further notify the board in writing within ten (10) days of the resumption of ~~the~~ practice ~~of pharmacy~~. ~~Such periods of time shall not apply to the reduction of the probation period.~~ Any failure to provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding ~~three years~~ thirty-six (36) months.

"Cessation of practice" means any ~~period of time exceeding 30 days~~ calendar month ~~in~~ during which respondent is not practicing as a pharmacist for at least _____ hours, as defined by Business and Professions Code section 4000 et seq ~~engaged in the practice of pharmacy as defined in Section 4052 of the Business and Professions Code~~. "Resumption of practice" means any calendar month during which respondent is practicing as a pharmacist for at least _____ hours as a pharmacist as defined by Business and Professions Code section 4000 et seq.

Option: Respondent is required to practice as a pharmacist in a licensed pharmacy setting that dispenses medication for a minimum of one year prior to the completion of probation. After the first year of probation, the board or its designee may consider a modification of this requirement. If respondent fails to comply with this requirement or a subsequent modification thereto, such failure shall be considered a violation of probation.

~~Option: Respondent shall work at least 40 hours in each calendar month as a pharmacist and at least an average of 80 hours per month in any six consecutive months. Failure to do so will be a violation of probation. If respondent has not complied with this~~

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~~condition during the probationary term, and respondent has presented sufficient documentation of his or her good faith efforts to comply with this condition, and if no other conditions have been violated, the board, in its discretion, may grant an extension of respondent's probation period up to one year without further hearing in order to comply with this condition.~~

~~14.~~15. Violation of Probation

If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order ~~which~~ that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended, until the petition to revoke probation or accusation is heard and decided.

~~If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty which was stayed.~~

~~15.~~16. Completion of Probation

Upon written notice by the board or its designee indicating successful completion of probation, respondent's license will be fully restored.

OPTIONAL CONDITIONS OF PROBATION

~~1. Actual Suspension~~

~~As part of probation, respondent is suspended from the practice of pharmacy for _____ beginning the effective date of this decision.~~

~~During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances.~~

~~Respondent shall not engage in any activity that requires the professional~~

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~~judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or an exemptee for any entity licensed by the board. Subject to the above restrictions, respondent may continue to own or hold an interest in any pharmacy in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

~~2.~~16. Restricted Practice ~~(Where this condition is imposed, optional condition #7 should also be imposed)~~

Respondent's practice of pharmacy shall be restricted to [specify setting or type of practice] for the first _____ years of probation. Respondent shall submit proof satisfactory to the board of compliance with this term of probation.

Option: Respondent shall not prepare, oversee or participate in the preparation of injectable sterile products during the first _____ year(s) of probation. Respondent shall submit proof satisfactory to the board of compliance with this term of probation. Failure to abide by this restriction or to timely submit proof to the board of compliance therewith shall be considered a violation of probation.

~~3.~~17. Pharmacist Examination

Respondent shall take and pass the _____ ~~section(s) of the pharmacist licensure examination as scheduled by the Board after the effective date of this decision at respondent's own expense~~[California Pharmacist Jurisprudence Examination (CPJE) and/or the North American Pharmacist Licensure Examination (NAPLEX)] within six (6) months of the effective date of this decision. If respondent fails to take and pass the examination(s) within six (6) months after the effective of this decision, respondent shall be automatically suspended from practice ~~upon written notice~~. Respondent shall not resume the practice of pharmacy until he or she takes and passes the ~~same section(s) at a subsequent examination~~ [CPJE and/or NAPLEX] and is notified, in writing, that he or she has passed the examination(s) and may resume practice. Respondent shall bear all costs of the examination(s) required by the board.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, ~~or~~ or be a consultant to any licensee of the ~~B~~board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the board.

During suspension, ~~R~~respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or ~~an exemptee~~ a designated representative for any entity licensed by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any ~~pharmacy~~ licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.
Failure to comply with this suspension shall be considered a violation of probation.

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If respondent fails to take and pass the [CPJE and/or NAPLEX] after four attempts, respondent shall successfully complete, at a minimum, sixteen (16) additional semester units of pharmacy education as approved by the board. Failure to complete coursework as required shall be considered a violation of probation. Failure to take ~~and pass~~ the examination(s) within one (1) year of the effective date of this decision shall be considered a violation of probation. ~~Suspension and probation shall be extended until respondent passes the examination and is notified in writing.~~

4. 18. **Mental Health Examination** (Appropriate for those cases where evidence demonstrates that mental illness or disability was a contributing cause of the violations.)

Within thirty (30) days of the effective date of this decision, and on a periodic basis as may be required by the board or its designee, respondent shall undergo, at his or her own expense, psychiatric evaluation(s) by a board-appointed or board-approved ~~psychiatrist or psychologist~~ licensed mental health practitioner. The approved evaluator shall be provided with a copy of the board's [accusation or petition to revoke probation] and decision. Respondent shall sign a release authorizing the evaluator to furnish the board with a current diagnosis and a written report regarding the respondent's judgment and ability to function independently as a pharmacist with safety to the public. Respondent shall comply with all the recommendations of the evaluator if directed by the board or its designee.

If the ~~psychiatrist or psychotherapist~~ evaluator recommends, and the board or its designee directs, respondent shall undergo psychotherapy. ~~Respondent shall, within 30 days of written notice of the need for psychotherapy, submit to the board for its prior approval, the recommended program for ongoing psychotherapeutic care. Respondent shall undergo and continue psychotherapy, at respondent's own expense, until further notice from the board. Respondent shall have the treating psychotherapist or psychiatrist submit written quarterly reports to the board as directed.~~ Within thirty (30) days of notification by the board that a recommendation for psychotherapy has been accepted, respondent shall submit to the board or its designee, for prior approval, the name and qualification of a licensed mental health practitioner of respondent's choice. Within thirty (30) days of approval thereof by the board, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved licensed mental health practitioner. Should respondent, for any reason, cease treatment with the approved licensed mental health practitioner, respondent shall notify the board immediately and, within thirty (30) days of ceasing treatment therewith, submit the name of a replacement licensed mental health practitioner of respondent's choice to the board for its prior approval. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved replacement. Failure to comply with any requirement or deadline stated by this paragraph shall be considered a violation of probation.

Upon approval of the initial or any subsequent licensed mental health practitioner, respondent shall undergo and continue treatment with that therapist, at respondent's own expense, until the therapist recommends in writing to the board, and the board or its designee agrees by way of a written notification to respondent, that no further psychotherapy is necessary. Upon receipt of such recommendation from the treating therapist, and before determining whether to accept or reject said recommendation, the board or its designee may require respondent to undergo, at respondent's expense, a mental health evaluation by a separate board-appointed or board-approved evaluator. If the approved evaluator recommends that respondent continue psychotherapy, the board or its designee may require respondent to continue psychotherapy.

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Psychotherapy shall be at least once a week unless otherwise approved by the board. Respondent shall provide the therapist with a copy of the board's [accusation or petition to revoke probation] and decision no later than the first therapy session. Respondent shall take all necessary steps to ensure that the treating therapist submits written quarterly reports to the board concerning respondent's fitness to practice, progress in treatment, and other such information as may be required by the board or its designee.

If at any time the approved evaluator or therapist determines that respondent is ~~determined to be~~ unable to practice safely or independently as a pharmacist, the licensed mental health practitioner shall notify the board immediately by telephone and follow up by written letter within three (3) working days. Upon notification from the board or its designee of this determination, ~~upon notification,~~ respondent shall ~~immediately cease practice~~ be automatically suspended and shall not resume practice until notified by the board that practice may be resumed.

Option: Commencing on the effective date of this decision, respondent shall not engage in the practice of pharmacy until notified in writing by the board that respondent ~~is~~ has been deemed psychologically fit to practice pharmacy safely, and the board or its designee approves said recommendation.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, ~~or~~ or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the board.

During suspension, ~~R~~respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or ~~an exemptee~~ a designated representative for any entity licensed by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any ~~pharmacy~~ licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

(Option language to be used in addition to standard language)
Option: If recommended by the evaluating ~~psychiatrist or psychotherapist~~ licensed mental health practitioner and approved by the board, respondent shall be suspended from practicing pharmacy until ~~the~~ respondent's treating ~~psycho~~therapist recommends, in writing, stating the basis therefor, that respondent can safely practice pharmacy, and the board or its designee approves said recommendation.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or

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controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, ~~or~~ or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the board.

During suspension, ~~R~~respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or ~~an exemptee~~ a designated representative for any entity licensed by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any ~~pharmacy~~ licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

~~5.~~19. **Psychotherapy** (Appropriate for those cases where the evidence demonstrates mental illness or alcohol or drug abuse was involved in the violations.)

Within thirty (30) days of the effective date of this decision, respondent shall submit to the board or its designee, for ~~its~~ prior approval, the name and qualifications of a licensed mental health practitioner of respondent's choice. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved licensed mental health practitioner. Should respondent, for any reason, cease treatment with the approved licensed mental health practitioner, respondent shall notify the board immediately and, within thirty (30) days of ceasing treatment, submit the name of a replacement psychotherapist or licensed mental health practitioner of respondent's choice to the board for its prior approval. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved replacement. Failure to comply with any requirement or deadline stated by this paragraph shall be considered a violation of probation.

Upon approval of the initial or any subsequent licensed mental health practitioner, respondent shall undergo and continue treatment with that therapist, at respondent's own expense, until the therapist recommends in writing to the board, and the board or its designee agrees by way of a written notification to respondent, that no further psychotherapy is necessary. Upon receipt of such recommendation from the treating therapist, and before determining whether to accept or reject said recommendation, the board or its designee may require respondent to undergo, at respondent's own expense, a mental health evaluation by a board-appointed or board-approved psychiatrist or psychologist. If the approved evaluator recommends that respondent continue psychotherapy, the board or its designee may require respondent to continue psychotherapy.

~~Therapy~~ Psychotherapy shall be at least once a week unless otherwise ~~determined~~ approved by the board. Respondent shall provide the therapist with a copy of the board's accusation and decision no later than the first therapy session. Respondent shall take all necessary steps to ensure that the treating therapist submits written quarterly reports to the board concerning respondent's fitness to practice, progress in treatment, and ~~to provide~~ such other information as may be required by the board or its designee.

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If at any time the treating therapist ~~finds~~ determines that respondent cannot practice safely or independently, the therapist shall notify the board immediately by telephone and followed up by written letter within three (3) working days. Upon notification from the board or its designee of this determination, respondent shall be automatically suspended and shall not resume practice until notified by the board that practice may be resumed.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the board.

During suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.
~~Upon approval of the licensed mental health practitioner, respondent shall undergo and continue treatment with that therapist and at respondent's own expense, until the board deems that no further psychotherapy is necessary. The board may require respondent to undergo a mental health evaluation(s) by a board appointed or board approved licensed mental health practitioner.~~

~~6.~~20. **Medical Evaluation** (Appropriate for those cases where the evidence demonstrates that the respondent has had a physical problem/disability which was a contributing cause of the violations and which may affect the respondent's ability to practice.)

Within thirty (30) days of the effective date of this decision, and on a periodic basis thereafter as may be required by the board or its designee, respondent shall undergo a medical evaluation, at respondent's own expense, by a board-appointed or board-approved physician who shall furnish a medical report to the board. The approved physician shall be provided with a copy of the board's [accusation or petition to revoke probation] and decision. A record of this notification must be provided to the board upon request. Respondent shall sign a release authorizing the physician to furnish the board with a current diagnosis and a written report regarding the respondent's ability to function independently as a pharmacist with safety to the public. Respondent shall comply with all the recommendations of the physician if directed by the board or its designee.

If ~~respondent is required by the board~~ the physician recommends, and the board or its designee directs, that respondent ~~to~~ undergo medical treatment, respondent shall, within thirty (30) days of written notice from the board, submit to the board or its designee, for prior approval, the name and qualifications of a licensed physician of respondent's choice. ~~for its prior approval,~~

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~~the name and qualifications of a physician of respondent's choice. Upon board approval of the treating physician, respondent shall undergo and continue medical treatment, with that physician and at respondent's own expense, until further notice from the board. Respondent shall have the treating physician submit written quarterly reports to the board. Should respondent, for any reason, cease treatment with the approved physician, respondent shall notify the board immediately and, within 30 days of ceasing treatment, submit the name of a replacement physician of respondent's choice to the board for its prior approval.~~ Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of treatment with the approved physician. Should respondent, for any reason, cease treatment with the approved physician, respondent shall notify the board immediately and, within thirty (30) days of ceasing treatment, submit the name of a replacement physician of respondent's choice to the board or its designee for prior approval. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of treatment with the approved replacement. Failure to comply with any deadline stated by this paragraph shall be considered a violation of probation.

Upon approval of the initial or any subsequent physician, respondent shall undergo and continue treatment with that physician, at respondent's own expense, until the treating physician recommends in writing to the board, and the board or its designee agrees by way of a written notification to respondent, that no further treatment is necessary. Upon receipt of such recommendation from the treating physician, and before determining whether to accept or reject said recommendation, the board or its designee may require respondent to undergo, at respondent's own expense, a medical evaluation by a separate board-appointed or board-approved physician. If the approved evaluating physician recommends that respondent continue treatment, the board or its designee may require respondent to continue treatment.

Respondent shall take all necessary steps to ensure that any treating physician submits written quarterly reports to the board concerning respondent's fitness to practice, progress in treatment, and other such information as may be required by the board or its designee.

If at any time an approved evaluating physician or respondent's approved treating physician determines that respondent is unable to practice safely or independently as a pharmacist, the evaluating or treating physician shall notify the board immediately by telephone and follow up by written letter within three (3) working days. Upon notification from the board or its designee of this determination, respondent shall be automatically suspended and shall not resume practice until notified by the board that practice may be resumed.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the board.

During suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated

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representative for any entity licensed by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

(Option language to be used in addition to standard language)
Option: ~~Upon~~ Commencing on the effective date of this decision, respondent shall not engage in the practice of pharmacy until notified in writing by the board ~~of its determination~~ that respondent has been deemed ~~is~~ medically fit to practice safely and independently, and the board or its designee approves said recommendation.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, ~~or~~ or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs or controlled substances. Respondent shall not resume practice until notified by the board.

During suspension, ~~R~~respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or ~~an exemptee~~a designated representative for any entity licensed by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any ~~pharmacy~~ licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

(Option language to be used in addition to standard language)
Option: If recommended by the evaluating physician and approved by the board, respondent shall be suspended from practicing pharmacy until the treating physician recommends, in writing, stating the basis therefor, that respondent can safely and independently resume the practice of a pharmacist, and the board or its designee approves said recommendation. Respondent shall not resume practice until notified by the board that practice may be resumed.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, ~~or~~ or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. Respondent shall not resume practice until

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notified by the board.

During suspension, Rrespondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or ~~an exempteea~~ designated representative for any entity licensed by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any ~~pharmacy~~ licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

~~7.~~21. ~~Rehabilitation Program~~ **Pharmacists Recovery Program (PRP)** (Appropriate for chemical dependency (alcohol, drugs), or psychiatric disorders (mental illness, emotional disturbance, gambling)

Within thirty (30) days of the effective date of this decision, respondent shall contact the Pharmacists Recovery Program (PRP) for evaluation, and shall immediately thereafter enroll, successfully participate in, and complete the treatment contract and any subsequent addendums as recommended and provided by the PRP and as approved by the board or its designee. The costs for PRP participation shall be borne by the respondent.

If respondent is currently enrolled in the PRP, said participation is now mandatory and as of the effective date of this decision is no longer considered a self-referral under Business and Professions Code section ~~43634~~362(c)(2)~~, as of the effective date of this decision~~. Respondent shall successfully participate in and complete his or her current contract and any subsequent addendums with the PRP.

Failure to timely contact or enroll in the PRP, or successfully participate in and complete the treatment contract and/or any addendums, shall be considered a violation of probation.

Probation shall be automatically extended until respondent successfully completes ~~his or her treatment contract~~ the PRP. Any person terminated from the PRP program shall be automatically suspended ~~upon notice~~ by the board. Respondent may not resume the practice of pharmacy until notified by the board in writing.

Any confirmed positive test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment shall result in the automatic suspension of practice by respondent and shall be considered a violation of probation. Respondent may not resume the practice of pharmacy until notified by the board in writing.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the board.

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During suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

Respondent shall pay administrative fees as invoiced by the PRP or its designee. Fees not timely paid to the PRP shall constitute a violation for probation. The board will collect unpaid administrative fees as part of the annual probation monitoring costs if not submitted to the PRP.

(Option language to be used in addition to standard language)
Option: Respondent shall work in a pharmacy setting with access to controlled substances for six (6) consecutive months before successfully completing probation. If respondent fails to do so, probation shall be automatically extended until this condition has been met. Failure to satisfy this condition within six (6) months beyond the original date of expiration of the term of probation shall be considered a violation of probation.

~~The board shall retain jurisdiction to institute action to terminate probation for any violation of this term.~~

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~~8.~~22. **Random Drug Screening** (If PRP provision is required, this term is also to be included to allow for continued fluid monitoring by the Board in cases where a respondent successfully completes the PRP before completion of the probation period; terms is also appropriate for those cases where the evidence demonstrates that the respondent may have a problem with chemical dependency (drugs, alcohol) but where the PRP is not required.)

Respondent, at his or her own expense, shall participate in random testing, including but not limited to biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or ~~a~~ other drug screening program ~~approved~~ as directed by the board or its designee. ~~The length of time shall be for the~~ Respondent may be required to participate in testing for the entire probation period and the frequency of testing will be determined by the board or its designee. At all times, respondent shall fully cooperate with the board or its designee, and shall, when directed, submit to such tests and samples for the detection of alcohol, narcotics, hypnotics, dangerous drugs or other controlled substances as the board or its designee may direct. Failure to timely submit to testing as directed shall ~~constitute~~ be considered a violation of probation. Upon request of the board or its designee, respondent shall provide documentation from a licensed practitioner that the prescription for a detected drug was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation. Any confirmed positive test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment shall be considered a violation of probation and ~~drug test~~ shall result in the ~~immediate~~ automatic suspension of practice of pharmacy by respondent. Respondent may not resume the practice of pharmacy until notified by the board in writing.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the board.

During suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

~~9.~~23. **Abstain from Drugs and Alcohol Use**

Respondent shall completely abstain from the possession or use of alcohol, controlled substances, dangerous drugs and their associated paraphernalia except when the drugs are lawfully prescribed by a licensed practitioner as part of a documented medical treatment. Upon request of the board or its designee, respondent shall provide documentation from the licensed

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practitioner that the prescription for the drug was legitimately issued and is a necessary part of the treatment of the respondent. ~~Respondent shall ensure that he or she is not in the same physical location as individuals who are using illicit substances even if respondent is not personally ingesting the drugs.~~ Failure to timely provide such documentation shall be considered a violation of probation. Respondent shall ensure that he or she is not in the same physical location as individuals who are using illicit substances even if respondent is not personally ingesting the drugs. Any possession or use of alcohol, controlled substances, or their associated paraphernalia not supported by the documentation timely provided, and/or any physical proximity to persons using illicit substances, shall be considered a violation of probation.

24. **Prescription Coordination and Monitoring of Prescription Use** (Appropriate for chemical dependency (alcohol, drugs), or psychiatric disorders (mental illness, emotional disturbance, gambling)

Within thirty (30) days of the effective date of this decision, respondent shall submit to the board, for its prior approval, the name and qualifications of a single physician, nurse practitioner, physician assistant, or psychiatrist of respondent's choice, who shall be aware of the respondent's history [with the use of alcohol, controlled substances, and/or dangerous drugs, and/or of mental illness, and/or of gambling addiction] and who will coordinate and monitor any prescriptions for respondent for dangerous drugs, controlled substances or mood-altering drugs. The approved practitioner shall be provided with a copy of the board's [accusation or petition to revoke probation] and decision. A record of this notification must be provided to the board upon request. Respondent shall sign a release authorizing the practitioner to communicate with the board about respondent's treatment(s). The coordinating physician, nurse practitioner, physician assistant, or psychiatrist shall report to the board on a quarterly basis for the duration of probation regarding respondent's compliance with this condition. If any substances considered addictive have been prescribed, the report shall identify a program for the time limited use of any such substances. The board may require that the single coordinating physician, nurse practitioner, physician assistant or psychiatrist be a specialist in addictive medicine, or consult a specialist in addictive medicine. Should respondent, for any reason, cease supervision by the approved practitioner, respondent shall notify the board immediately and, within thirty (30) days of ceasing treatment, submit the name of a replacement physician, nurse practitioner, physician assistant, or psychiatrist of respondent's choice to the board or its designee for its prior approval. Failure to timely submit the selected practitioner or replacement practitioner to the board for approval, or to ensure the required reporting thereby on the quarterly reports, shall be considered a violation of probation.

If at any time an approved practitioner determines that respondent is unable to practice safely or independently as a pharmacist, the practitioner shall notify the board immediately by telephone and follow up by written letter within three (3) working days. Upon notification from the board or its designee of this determination, respondent shall be automatically suspended and shall not resume practice until notified by the board that practice may be resumed.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of

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dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the board.

During suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

~~10.~~25. Community Services Program

Within sixty (60) days of the effective date of this decision, respondent shall submit to the board or its designee, for ~~its~~ prior approval, a community service program in which respondent shall provide free health-care related services on a regular basis to a community or charitable facility or agency for at least _____ hours per _____ for the first _____ of probation. Within thirty (30) days of board approval thereof, respondent shall submit documentation to the board demonstrating commencement of the community service program. A record of this notification must be provided to the board upon request. Respondent shall report on progress with the community service program in the quarterly reports. Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.

~~11.~~26. Restitution ~~(For Pharmacist and Premises)~~ (Appropriate in cases of drug diversion, theft, fraudulent billing, or patient harm resulting from negligence or incompetence.)

Within _____ days of the effective date of this decision, respondent shall pay restitution to _____ in the amount of $ _____. Failure to make restitution by this deadline shall be considered a violation of probation.

~~12.~~27. Remedial Education

Within [thirty (30), sixty (60), ninety (90)] days of the effective date of this decision, respondent shall submit to the board or its designee, for ~~its~~ prior approval, an appropriate program of remedial education related to [the grounds for discipline]. The program of remedial education shall consist of at least _____ hours, which shall be completed within _____ months/year at respondent's own expense. ~~The period of probation shall be extended until such remedial education is successfully completed and written proof, in a form acceptable to the board, is provided to the board.~~ All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes.

Failure to timely submit or complete the approved remedial education ~~as set forth hereinabove is grounds for the filing of a petition to revoke probation~~ shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof, in a form acceptable to the board, is provided to the board or its designee.

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Following the completion of each course, the board ~~may administer~~ or its designee may require the respondent, at his or her own expense, to take an approved ~~an~~ examination to test the respondent's knowledge of the course. If the respondent does not achieve a passing score on the examination, this failure shall be considered a violation of probation. Any such examination failure shall require respondent to take another course approved by the board in the same subject area.

Option: Respondent shall be restricted from the practice of [areas where a serious deficiency has been identified] until the remedial education program has been successfully completed.

28. Pharmacy Self-Assessment Mechanism

Within the first year of probation, respondent shall complete the Pharmacist Self-Assessment Mechanism (PSAM) examination provided by the National Association of Boards of Pharmacy (NABP). Respondent shall submit a record of completion to the board demonstrating he/she has completed this examination. Respondent shall bear all costs for the examination. Continuing education hours received for this examination shall not be used as part of the required continuing education hours for renewal purposes.

Failure to timely complete the PSAM or submit documentation thereof shall be considered a violation of probation.

Option A: Respondent shall waive any rights to confidentiality and provide examination results to the board or its designee.

Option B: (This term must be accompanied by the "Remedial Education" term. [Include/Modify Remedial Education Term to Conform].) Respondent shall waive any rights to confidentiality and provide examination results to the board or its designee. Based on the results of the examination, the board shall determine which courses are appropriate for remedial education.

~~13.~~29. ~~Pharmacy~~ Intern Pharmacist Experience ~~(For Intern Pharmacist)~~

Within ninety (90) days of the effective date of this decision, respondent shall submit to the board or its designee, for ~~its~~ prior approval, a pharmacy intern training program consisting of _____ hours to be served as an intern pharmacist in a community -and/or institutional pharmacy as directed. Respondent shall successfully complete the intern hours within the first year of probation and shall, by no later than one (1) year from the effective date of this decision, submit ~~a "Pharmacy Intern Experience Affidavit" and "Pharmacy Intern Hours Affidavit" signed by a currently licensed pharmacist not on probation with the board~~ proof satisfactory to the board of completion of this experience signed under penalty of perjury by both the respondent and supervising pharmacist. Failure to timely complete or document the required intern experience shall be considered a violation of probation.

~~14.~~30. Supervised Practice

During the period of probation, rRespondent shall practice only under the supervision of a licensed pharmacist not on probation with the board. Upon and after the effective date of this decision, rRespondent shall not practice pharmacy and his or her license shall be automatically suspended until ~~the~~ a supervisor is approved by the board or its designee. The supervision shall be, as required by the board or its designee, either:

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Continuous -- At least 75% ~~to 100%~~ of a work week
Substantial - At least 50% of a work week
Partial - At least 25% of a work week
Daily Review - Supervisor's review of probationer's daily activities within 24 hours

Within thirty (30) days of the effective date of this decision, respondent shall have his or her supervisor submit notification to the board in writing stating that the supervisor has read the decision in case number _____ and is familiar with the required level of supervision as determined by the board or its designee. It shall be the respondent's responsibility to ensure that his or her employer(s), pharmacist-in-charge and/or supervisor(s) submit timely acknowledgement(s) to the board. Failure to cause the direct supervisor and the pharmacist-in-charge to submit timely acknowledgements to the board shall be considered a violation of probation.

If respondent changes employment, it shall be the respondent's responsibility to ensure that his or her employer(s), pharmacist-in-charge and/or supervisor(s) submit timely acknowledgement(s) to the board. ~~r~~Respondent shall have his or her new supervisor, within fifteen (15) days after employment commences, submit notification to the board in writing stating the direct supervisor and pharmacist-in-charge have read the decision in case number _____ and is familiar with the level of supervision as determined by the board. Respondent shall not practice pharmacy and his or her license shall be automatically suspended until the board or its designee approves a new supervisor. Failure to cause the direct supervisor and the pharmacist-in-charge to submit timely acknowledgements to the board shall be considered a violation of probation.

Within ten (10)~~,~~ days of leaving employment, respondent shall notify the board in writing.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the board.

During suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

~~15.~~31. No Supervision of Ancillary Personnel

During the period of probation, ~~R~~respondent shall not supervise any ancillary personnel,

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including, but not limited to, ~~registered~~ pharmacy technicians or ~~exemptees~~ designated representatives~~,~~ ~~of~~in any entity licensed by the board.

Failure to comply with this provision shall be considered a violation of probation.

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~~16.~~32. No Ownership of Licensed Premises

Respondent shall not own, have any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

Option: Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If respondent currently owns or has any legal or beneficial interest in, or serves as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

~~17.~~33. Separate File of Records (For pharmacist owners and pharmacists-in-charge)

Respondent shall maintain and make available for inspection a separate file of all records pertaining to the acquisition or disposition of all controlled substances. Failure to maintain such file or make it available for inspection shall be considered a violation of probation.

~~18.~~34. Report of Controlled Substances (For pharmacist owners and pharmacists-in-charge)

Respondent shall submit quarterly reports to the board detailing the total acquisition and disposition of such controlled substances as the board may direct. Respondent shall specify the manner of disposition (e.g., by prescription, due to burglary, etc.) or acquisition (e.g., from a manufacturer, from another retailer, etc.) of such controlled substances. Respondent shall report on a quarterly basis or as directed by the board. The report shall be delivered or mailed to the board no later than ten (10) days following the end of the reporting period. Failure to timely prepare or submit such reports shall be considered a violation of probation.

~~19.~~35. No Access to Controlled Substances

During the period of probation and as directed by the board or its designee, Rrespondent shall not order, possess, dispense or otherwise have access to any controlled substance(s) in Schedule II, III, IV or V (Health and Safety Code sections 11055-11058 inclusive). Respondent shall not order, receive or retain any ~~triplicate~~ security prescription forms. Failure to comply with this restriction shall be considered a violation of probation.

~~20.~~36. Criminal Probation/Parole Reports

Respondent shall provide a copy of the conditions of any criminal probation/parole to the board, in writing, within ten (10) days of the issuance or modification of those conditions. Respondent shall provide the name of his or her probation/parole officer to the board, in writing, within ten

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(10) days after that officer is designated or a replacement for that officer is designated. Respondent shall provide a copy of all criminal probation/parole reports to the board within ten (10) days after respondent receives a copy of such a report. Failure to timely make any of the submissions required hereby shall be considered a violation of probation.

~~21.~~37. Consultant for Owner or Pharmacist-in-Charge

(Option #1 for pharmacist owners - primarily intended for appropriate cases where the respondent is the sole owner and pharmacist-in-charge of his or her own pharmacy, the standard language should be used in most cases.)

During the period of probation, Rrespondent shall not supervise any intern pharmacist, ~~perform any of the duties of a preceptor~~ or serve as a consultant to any entity licensed by the board. Respondent may be a pharmacist-in-charge. However, if during the period of probation respondent serves as a pharmacist-in-charge, respondent shall retain an independent consultant at his or her own expense who shall be responsible for reviewing pharmacy operations on a [monthly/quarterly] basis for compliance by respondent with state and federal laws and regulations governing the practice of pharmacy and for compliance by respondent with the obligations of a pharmacist-in-charge. The consultant shall be a pharmacist licensed by and not on probation with the board and whose name shall be submitted to the board or its designee, for ~~its~~ prior approval, within thirty (30) days of the effective date of this decision. Respondent shall not be a pharmacist-in-charge at more than one pharmacy or at any pharmacy of which he or she is not the sole owner. Failure to timely retain, seek approval of, or ensure timely reporting by the consultant shall be considered a violation of probation.

(Option #2 - appropriate for pharmacists who are not pharmacy owners, but who wish, because of their current employment, to remain as the pharmacist-in-charge, and have provided ~~documentation~~ documented mitigating evidence to warrant this option.)

During the period of probation, Rrespondent shall not supervise any intern pharmacist, ~~perform the duties of a preceptor~~ or serve as a consultant to any entity licensed by the board. In the event that the respondent is currently the pharmacist-in-charge of a pharmacy, the pharmacy shall retain an independent consultant at its own expense who shall be responsible for reviewing pharmacy operations on a [monthly/quarterly] basis for compliance by respondent with state and federal laws and regulations governing the practice of pharmacy and for compliance by respondent with the obligations of a pharmacist-in-charge. The consultant shall be a pharmacist licensed by and not on probation with the board and whose name shall be submitted to the board or its designee, for ~~its~~ prior approval. ~~w~~Within thirty (30) days of the effective date of this decision. Respondent shall not be a pharmacist-in-charge at more than one pharmacy or at any pharmacy of which he or she is not the current PIC. The board may, in case of an employment change by respondent or for other reasons as deemed appropriate by the board or its designee, preclude the respondent from acting as a pharmacist-in-charge. Failure to timely retain, seek approval of, or ensure timely reporting by the consultant shall be considered a violation of probation.

~~22.~~38. Tolling of Suspension

During the period of suspension, respondent shall not leave California for any period exceeding ten (10) days, regardless of purpose (including vacation). Any such absence in excess of the (10) days during suspension shall be considered a violation of probation. Moreover, any absence from California during the period of suspension exceeding ten (10) days shall toll the

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suspension, i.e., the suspension shall be extended by one day for each day over ten (10) days respondent is absent from California. During any such period of tolling of suspension, respondent must nonetheless comply with all terms and conditions of probation.

Respondent must notify the board in writing within ten (10) days of departure, and must further notify the board in writing within ten (10) days of return. The failure to provide such notification(s) shall constitute a violation of probation. Upon such departure and return, respondent shall not resume the practice of pharmacy until notified by the board that the period of suspension has been satisfactorily completed.

~~If respondent leaves California to reside or practice outside this state, for any period exceeding 10 days (including vacation), respondent must notify the board in writing of the dates of departure and return. Periods of residency or practice outside the state or any absence exceeding a period of 10 days shall not apply to the reduction of the suspension period.~~

~~Respondent shall not practice pharmacy upon returning to this state until notified by the board that the period of suspension has been completed.~~

39. Surrender of DEA Permit

Within thirty (30) days of the effective date of this decision, respondent shall surrender his or her federal Drug Enforcement Administration (DEA) permit to the DEA, for cancellation. Respondent shall provide documentary proof of such cancellation to the board or its designee. Respondent is prohibited from prescribing until the board has received satisfactory proof of cancellation. Thereafter, respondent shall not apply/reapply for a DEA registration number without the prior written consent of the board or its designee.

Option: Respondent may obtain a DEA permit restricted to Schedule(s) _____ controlled substance(s).

Option: Respondent shall not order, receive, or retain any federal order forms, including 222 forms, for controlled substances.

40. Ethics Course

Within sixty (60) calendar days of the effective date of this decision, respondent shall enroll in a course in ethics, at respondent's expense, approved in advance by the board or its designee. Failure to initiate the course during the first year of probation, and complete it within the second year of probation, is a violation of probation.

Respondent shall submit a certificate of completion to the board or its designee within five days after completing the course.

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PHARMACY TECHNICIAN

The board files cases against pharmacy technicians where the violation(s) involve significant misconduct on the part of the licensee. The board believes that revocation is typically the appropriate penalty when grounds for discipline are found to exist. Grounds for discipline include, but are not limited to the following violation(s) of law(s) involving:

- Possession of dangerous drugs and/or controlled substances
- Use of dangerous drugs and/or controlled substances
- Possession for sale of dangerous drugs and/or controlled substances
- Personal misuse of drugs or alcohol

If revocation is not imposed, the board recommends a minimum ~~of a~~ Category III level of discipline be imposed on the pharmacy technician. This would include suspension and probation.

In addition, a pharmacy technician would be required to obtain certification ~~from the Pharmacy Technician Certification Board (PTCB)~~as defined by Business and Professions Code section 4202(a)(4) prior to resuming work as a pharmacy technician. The board believes that certification prior to resuming work is always warranted in cases where a pharmacy technician ~~registration~~ license is disciplined but not revoked.

Pharmacy technicians are issued a ~~registration,~~license based on minimal education, ~~or~~ training requirements or certification. No examination is required for issuance of the registration. Pharmacy technicians are not independent practitioners and must work under the supervision of a pharmacist. To place a pharmacy technician on probation places an additional burden on the pharmacist (who may or may not be on probation) to ensure that the respondent pharmacy technician complies with the terms and conditions of his or her probation.

TERMS OF PROBATION – PHARMACY TECHNICIAN

A minimum three-year probation period has been established by the board as appropriate in most cases where probation is imposed. A minimum five-year probation period has been established by the board as appropriate where self-administration or diversion of controlled substances is involved. Terms and conditions are imposed to provide consumer protection and to allow the probationer to demonstrate rehabilitation. A suspension period may also be required as part of the probation order. The board prefers that any stayed order be for revocation rather than for some period of suspension.

Probation conditions are divided into two categories: (1) standard conditions that shall appear in ~~all~~ all probation cases, and (2) optional conditions that depend on the nature and circumstances of a particular case. These conditions may vary depending on the nature of the offense(s).

The board may also impose any other condition appropriate to the case where the condition is not contrary to public policy.

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CATEGORY OF VIOLATIONS AND RECOMMENDED PENALTIES

CATEGORY III - Penalty

Minimum: Revocation; Revocation stayed, 90 days actual suspension, three years probation. All standard terms and conditions shall be included and optional terms and conditions as appropriate.

Maximum: Revocation

Applies to all applicable statutes and regulations

MODEL DISCIPLINARY LANGUAGE – PHARMACY TECHNICIAN

The following standardized language shall be used in every decision where the order of condition is imposed.

Revocation ~~– Single Cause~~

Pharmacy ~~T~~technician ~~registration~~ license number _____, issued to respondent _____ is revoked. Respondent shall relinquish his or her ~~pocket~~ technician ~~registration~~ license to the board within ten (10) days of the effective date of this decision. Respondent may not reapply or petition the board for reinstatement of his or her revoked technician ~~registration~~ license for three (3) years from the effective date of this decision.

A condition of reinstatement shall be that the respondent is certified as defined in Business and Professions Code section 4202(a)(4)~~by the Pharmacy Technician Certification Board (PTCB)~~ and provides satisfactory proof of certification to the board.

Respondent shall pay to the board its costs of investigation and prosecution in the amount of $_____ within fifteen (15) days of the effective date of this decision.

Option: As a condition precedent to ~~Upon~~ reinstatement of his or her revoked technician ~~registration~~ license respondent shall reimburse the board for its costs of investigation and prosecution in the amount of $_____~~.~~ ~~and s~~Said amount shall be paid in full prior to the reapplication or reinstatement of his or her revoked technician license, unless otherwise ordered by the board ~~of his or her technician registration. If the respondent fails to pay the amount specified, his or her technician registration shall remain revoked~~.

~~**Revocation – Multiple Causes**~~

~~Technician registration number _____, issued to respondent _____ is revoked pursuant to Determination of Issues _____, separately and together. Respondent shall relinquish his or her pocket technician registration to the board within 10 days of the effective date of this decision. Respondent may not petition the board for reinstatement of his or her revoked technician registration for three years from the effective date of this decision. A condition of reinstatement shall be that the respondent is certified by the Pharmacy Technician Certification Board (PTCB) and provides satisfactory proof of certification to the board.~~

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~~Respondent shall pay to the board its costs of investigation and prosecution in the amount of $_____ within 15 days of the effective date of this decision.~~

~~**Option:** Upon reinstatement of his or her technician registration respondent shall reimburse the board for its costs of investigation and prosecution in the amount of $_____, and said amount shall be paid in full prior to the reinstatement of his or her technician registration. If the respondent fails to pay the amount specified, his or her technician registration shall remain revoked.~~

Suspension ~~– Single Cause~~

As part of probation, ~~Technician registration number _____, issued to~~ respondent _____ ~~is~~ is suspended from working as a pharmacy technician for ~~for a period of _____~~ beginning the effective date of this decision.

During suspension, respondent shall not enter any pharmacy area or any portion of or any other board licensed premises (wholesaler, veterinary food-animal drug retailer or any other distributor of drugs) any drug manufacturer, or any other location where dangerous drugs and devices or controlled substances are maintained. Respondent shall not do any act involving drug selection, selection of stock, manufacturing, compounding or dispensing; nor shall respondent manage, administer, or assist any licensee of the board. Respondent shall not have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances.

Respondent shall not direct, control or perform any aspect of the practice of pharmacy. Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

~~**Suspension – Multiple Causes**~~

~~Technician registration number _____, issued to respondent is suspended for a period of _____ pursuant to Determination of Issues _____, separately and together. All suspensions shall run concurrently. Respondent is suspended from the duties of a pharmacy technician for _____ beginning the effective date of this decision.~~

Standard Stay/Probation Order

Pharmacy ~~T~~technician ~~registration~~ license number _____ ~~issued to _____~~ is revoked; however, the revocation is stayed and respondent is placed on probation for _____ years upon the following terms and conditions:

Issuance of Probationary License (In cases where a Statement of Issues has been filed.)

Upon satisfaction of all statutory and regulatory requirements for issuance of a license, a license shall be issued to respondent and immediately revoked; the order of revocation is stayed and respondent is placed on probation for _____ years upon the following terms and conditions:

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Surrender

Respondent surrenders pharmacy technician ~~registration~~ license number _____ as of the effective date of this decision. Respondent shall relinquish his or her ~~pocket~~ pharmacy technician ~~registration~~ license to the board within ten (10) days of the effective date of this decision.

The surrender of respondent's license and the acceptance of the surrendered license by the board shall constitute the imposition of discipline against respondent. This decision constitutes a record of discipline and shall become a part of respondent's license history with the board.

Respondent understands and agrees that if he or she ever files an application for licensure or a petition for reinstatement in the State of California, the board shall treat it as a new application for licensure.

Respondent may not ~~re~~apply for any license, permit, or ~~technician~~ registration ~~of~~ from the board for three (3) years from the effective date of this decision. Respondent stipulates that should ~~respondent~~ he or she apply for any ~~technician registration~~ license from the board on or after the effective date of this decision, all allegations set forth in the [accusation or petition to revoke probation] shall be deemed to be true, correct and admitted by respondent when the board determines whether to grant or deny the application. Respondent shall satisfy all requirements applicable to that license as of the date the application is submitted to the board, including, but not limited to certification by a nationally recognized body prior to the issuance of a new license. Respondent is required to report this surrender as disciplinary action. ~~Should respondent apply for any new license, respondent will be subject to all terms and conditions not previously satisfied.~~

~~Respondent shall meet all requirements applicable to that technician registration as of the date the application is submitted to the board, including, but not limited to certification by a nationally recognized body prior to the issuance of a new registration.~~

Respondent further stipulates that he or she shall reimburse the board for its costs of investigation and prosecution in the amount of $_____ within _____ days of the effective date of this decision.

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Option: Respondent stipulates that should he or she apply for any ~~technician registration~~ license from the board on or after the effective date of this decision, ~~that~~ investigation and prosecution costs in the amount of $_____ shall be paid to the board prior to issuance of the ~~technician registration~~ license.

Public Reprimand

It is hereby ordered that a public reprimand be issued against pharmacy technician license, _____. Respondent is required to report this reprimand as a disciplinary action.

Adoption of Stipulation

It is understood by respondent that, in deciding whether to adopt this stipulation, the board may receive oral and written communication from its staff and the ~~Attorney General's~~ Office of the Attorney General. Communications pursuant to this paragraph shall not disqualify the board or other persons from future participation in this or any other matter affecting respondent. In the event this settlement is not adopted by the board, the stipulation will not become effective and may not be used for any purpose, except this paragraph, which shall remain in effect.

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STANDARD CONDITIONS – To be included in all probation decisions/orders.

~~Term Number: (Numbers reflect actual term and condition numbers as listed beginning with page _____.)~~

1. Certification Prior to Resuming Work
2. Obey aAll Laws
3. Reporting to the Board
4. Interview with the Board
5. Cooperatione with Board Staff
6. Notice to Employers
7. Reimbursement of Board Costs
8. Probation Monitoring Costs
9. Status of License
10. License Surrender While on Probation/Suspension
~~10.~~11. Notification of a Change in Name, Residence Address, ~~Employment~~/Mailing Address or Employment ~~Change~~
~~11.~~12. Tolling of Probation
~~12.~~13. Violation of Probation
~~13.~~14. Completion of Probation
~~14.License Surrender While on Probation/Suspension~~

OPTIONAL CONDITIONS

~~Term Number: (Numbers reflect actual term and condition numbers as listed beginning with page _____.)~~

~~1.Actual Suspension~~
~~2.~~15. No Ownership of Licensed Premises
~~3.~~16. Attend Substance Abuse Recovery Relapse Prevention and Support Groups
~~4.~~17. Random Drug Screening
~~5.~~18. Work Site Monitor
~~6.~~19. Notification of Departure
~~7.~~20. Abstain from Drugs and Alcohol Use
~~8.~~21. Tolling of Suspension
22. Restitution

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STANDARD CONDITIONS: TO BE INCLUDED IN ALL PROBATIONS

~~1.~~1. Certification Prior to Resuming Work

Respondent shall be automatically suspended from working as a pharmacy technician until he or she is certified ~~by the Pharmacy Technician Certification Board (PTCB)~~as defined by Business and Professions Code section 4202(a)(4) and provides satisfactory proof of certification to the board. Respondent shall not resume working as a pharmacy technician until notified by the board. Failure to achieve certification within one (1) year shall be considered a violation of probation. Respondent shall not resume working as a pharmacy technician until notified by the board.

During suspension, respondent shall not enter any pharmacy area or any portion of any other board ~~the~~ licensed premises ~~of a~~ (wholesaler, veterinary food-animal drug retailer or any other distributor of drugs) ~~which is licensed by the board, or~~ any drug manufacturer, or any other location where dangerous drugs and devices or controlled substances are maintained. Respondent shall not do any act involving drug selection, selection of stock, manufacturing, compounding or dispensing; nor shall respondent manage, administer, ~~or be a consultant to~~ or assist any licensee of the board~~,~~. Respondent shall not ~~or~~ have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances. Respondent shall not resume work until notified by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any ~~entity~~ licensed premises by the board in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

~~2.~~2. Obey All Laws

Respondent shall obey all state and federal laws and regulations ~~substantially related to or governing the practice of pharmacy~~.

Respondent shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

~~3.~~3. Reporting to the Board

Respondent shall report to the board quarterly, on a schedule as directed by the board or its

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designee. The report shall be made either in person or in writing, as directed. Among other requirements, Rrespondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, lif the final probation report is not made as directed, probation shall be automatically extended ~~automatically~~ until such time as the final report is made and accepted by the board.

~~4.~~4. Interview with the Board

Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, ~~upon request at various~~ such intervals and ~~at a~~ locations as are ~~to be~~ determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear at two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

~~5.~~5. Cooperation~~e~~ with Board Staff

Respondent shall cooperate with the board's inspectional program and ~~in~~ with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his or her probation. Failure to ~~comply~~ cooperate shall be considered a violation of probation.

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~~6.~~6. Notice to Employers

During the period of probation, Rrespondent shall notify all present and prospective employers of the decision in case number _____ and the terms, conditions and restrictions imposed on respondent by the decision, as follows:~~.~~

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause his or her direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and owner ~~employer~~ to report to the board in writing acknowledging that the listed individual(s) has/have ~~employer has~~ read the decision in case number _____ and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgement(s) to the board.

If respondent works for or is employed by or through a pharmacy employment service, respondent must notify ~~the~~ his or her direct supervisor, pharmacist-in-charge and/~~or~~ owner at every pharmacy of the terms and conditions of the decision in case number _____ in advance of the respondent commencing work at each pharmacy. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy employment service, respondent shall cause his or her direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that he or she has read the decision in case number _____ and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgements to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision shall include any full-time, part-time, temporary or relief service or pharmacy management service as a pharmacy technician or in any position for which a pharmacy technician license is a requirement or criterion for employment, whether the respondent is considered an employee, ~~or~~ independent contractor or volunteer.

~~7.~~7. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, Rrespondent shall pay to the board its costs of investigation and prosecution in the amount of $_____. Respondent shall make said payments as follows: _____. There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondent shall not relieve respondent of his or her responsibility to reimburse the board its costs of investigation and prosecution.

~~Option: If respondent fails to make any payment by the directed deadline(s), the stay shall~~

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~~terminate and the license shall be revoked without further notice or opportunity to be heard.~~

~~8.~~8. Probation Monitoring Costs

Respondent shall pay ~~the~~ any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board ~~at the end of each year of probation~~ on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

~~9.~~9. Status of License

Respondent shall, at all times while on probation, maintain an active, current pharmacy technician ~~registration/certification~~ license with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.

If respondent's pharmacy technician ~~registration/certification~~ license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication, respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

10. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent cease work due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his or her pharmacy technician license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the board.

Upon acceptance of the surrender, respondent shall relinquish his or her pharmacy technician license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent may not reapply for any license, permit, or registration from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

~~10.~~11. Notification of a Change in Name, Residence Address, ~~Employment/~~Mailing Address or Employment~~Change~~

Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, ~~and/or~~ the address of the new employer, the name of the supervisor ~~or~~ and owner, and the work schedule~~,~~ if known. Respondent shall further notify the board in writing within ten (10) days of a change in name, residence address and mailing address, or phone number.

Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

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~~11.~~12. Tolling of Probation

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a pharmacy technician in California for a minimum of _____ hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation.

~~It is a violation of probation for respondent to work less than _____ hours per month as a pharmacy technician/exemptee.~~ Should respondent, regardless of residency, for any reason (including vacation) cease ~~practicing~~ working as a pharmacy technician ~~or an exemptee~~ for a minimum of _____ hours per calendar month in California, respondent must notify the board in writing within ten (10) days of cessation of ~~practice~~ work and must further notify the board in writing within ten (10) days of ~~or~~ the resumption of the ~~practice~~ work. ~~Such periods of time shall not apply to the reduction of the probation period.~~ Any failure to provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding ~~three consecutive years~~ thirty-six (36) months.

"Cessation of ~~practice~~work" means ~~any period of time exceeding 30 days~~ calendar month during ~~in~~ which respondent is not ~~engaged in the practice of~~ working for at least _____ hours as a pharmacy technician, as defined in ~~section _____ of the~~ Business and Professions Code section 4115. "Resumption of work" means any calendar month during which respondent is working as a pharmacy technician for at least _____ hours as a pharmacy technician as defined by Business and Professions Code section 4115.

~~12.~~13. Violation of Probation

If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

_____If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order ~~which~~ that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction, and the period of probation shall be automatically extended, until the petition to revoke probation or accusation is heard and decided.

~~If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and~~

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~~to impose the penalty which was stayed.~~

~~13.~~14. Completion of Probation

Upon written notice by the board indicating successful completion of probation, respondent's pharmacy technician ~~registration~~ license will be fully restored.

~~14. License Surrender While on Probation/Suspension~~

~~Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his or her license to the board for surrender. The board shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation.~~

~~Upon acceptance of the surrender, respondent shall relinquish his or her pocket license to the board within 10 days of notification by the board that the surrender is accepted. Respondent may not reapply for any license from the board for three years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.~~

OPTIONAL CONDITIONS OF PROBATION

~~4. Actual Suspension~~

~~As part of probation, respondent is suspended from the duties of a pharmacy technician for _____ beginning the effective date of this decision.~~

~~During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not do any act involving drug selection, selection of stock, manufacturing, compounding or dispensing; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any entity licensed by the board in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

~~During suspension, respondent shall not perform any of the duties of a pharmacy technician as provided by Section 1793.2 of the California Code of Regulations.~~

~~2.~~15. No Ownership of Licensed Premises

Respondent shall not own, have any legal or beneficial interest in, or serve as a manager,

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administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

Option: Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If respondent currently owns or has any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective of this decision. Violation of this restriction shall be considered a violation of probation.

~~3.~~16. Attend Substance Abuse Recovery Relapse Prevention and Support Groups
(Appropriate for those cases with chemical dependency (alcohol, drugs))

Within thirty (30) days of the effective date of this decision, respondent shall begin regular attendance at a ~~board approved~~ recognized and established substance abuse recovery support group in California, (e.g., Alcoholics Anonymous, ~~Cocaine~~ Narcotics Anonymous, etc.,) which has been approved by the board or its designee. Respondent must attend at least one group meeting per week unless otherwise directed by the board or its designee. Respondent shall continue regular attendance and submit signed and dated documentation confirming attendance with each quarterly report for the duration of probation. Failure to attend or submit documentation thereof shall be considered a violation of probation.

~~4.~~17. Random Drug Screening (Appropriate for those cases with chemical dependency (alcohol, drugs))

Respondent, at his or her own expense, shall participate in random testing, including but not limited to biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or ~~a~~ other drug screening program ~~approved~~ as directed by the board or its designee. ~~The length of time shall be for the~~ Respondent may be required to participate in testing for the entire probation period and the frequency of testing will be determined by the board or its designee. At all times respondent shall fully cooperate with the board or its designee, and shall, when directed, submit to such tests and samples for the detection of alcohol, narcotics, hypnotics, dangerous drugs or other controlled substances as the board or its designee may direct. Failure to timely submit to testing as directed shall ~~constitute~~ be considered a violation of probation. Upon request of the board or its designee, respondent shall provide documentation from a licensed practitioner that the prescription for a detected drug was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation. Any confirmed positive ~~drug~~ test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment shall be considered a violation of probation and shall result in the ~~immediate~~ automatic suspension of ~~practice~~ work by respondent. Respondent may not resume ~~the practice of pharmacy~~ work as a pharmacy technician until notified by the board in writing.

During suspension, respondent shall not enter any pharmacy area or any portion of or any other board licensed premises (wholesaler, veterinary food-animal drug retailer or any other

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distributor of drugs) any drug manufacturer, or any other location where dangerous drugs and devices or controlled substances are maintained. Respondent shall not do any act involving drug selection, selection of stock, manufacturing, compounding or dispensing; nor shall respondent manage, administer, or assist any licensee of the board. Respondent shall not have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances. Respondent shall not resume work until notified by the board.

Respondent shall not direct, control or perform any aspect of the practice of pharmacy. Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

~~5.~~**18. Work Site Monitor** (Appropriate for those cases with chemical dependency (alcohol, drugs))

Within ten (10) days of the effective date of this decision, respondent shall identify a work site monitor, for prior approval by the board, who shall be responsible for supervising respondent during working hours. ~~The~~ Respondent shall be responsible for ensuring that the work site monitor ~~shall report~~ reports in writing to the board quarterly. Should the designated work site monitor determine at any time during the probationary period that respondent has not maintained sobriety, he or she shall notify the board immediately, either orally or in writing as directed. Should respondent change employment, a new work site monitor must be designated, for prior approval by the board, within ten (10) days of commencing new employment. Failure to identify an acceptable initial or replacement work site monitor, or to ensure quarterly reports are submitted to the board, shall be considered a violation of probation.

~~6.~~**19. Notification of Departure** (Appropriate for those cases with chemical dependency (alcohol, drugs))

~~If respondent leaves~~ Prior to leaving the probationary geographic area designated by the board or its designee for a period greater than twenty-four (24) hours, respondent shall notify the board verbally and in writing of the dates of departure and return~~, prior to leaving~~. Failure to comply with this provision shall be considered a violation of probation.

~~7.~~**20. Abstain from Drugs and Alcohol Use** (Appropriate for those cases with chemical dependency (alcohol, drugs))

Respondent shall completely abstain from the possession or use of alcohol, controlled substances, dangerous drugs and their associated paraphernalia except when the drugs are lawfully prescribed by a licensed practitioner as part of a documented medical treatment. Upon request of the board or its designee, respondent shall provide documentation from the licensed practitioner that the prescription for the drug was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation. ~~Respondent shall ensure that he or she is not in the same physical location as individuals who are using illicit substances even if respondent is not personally ingesting the drugs. Additionally, respondent shall cause the prescribing practitioner to notify the board in writing, indicating their awareness of the chemical dependency. Additionally, respondent shall cause the prescribing physician to notify the board in writing, indicating their awareness of the chemical dependency.~~ Respondent shall ensure that he or she

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is not in the same physical location as individuals who are using illicit substances even if respondent is not personally ingesting the drugs. Any possession or use of alcohol, controlled substances, or their associated paraphernalia not supported by the documentation timely provided, and/or any physical proximity to persons using illicit substances, shall be considered a violation of probation.

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~~8.~~21. Tolling of Suspension

During the period of suspension, respondent shall not leave California for any period exceeding ten (10) days, regardless of purpose (including vacation). Any such absence in excess of ten (10) days during suspension shall be considered a violation of probation. Moreover, any absence from California during the period of suspension exceeding ten (10) days shall toll the suspension, i.e., the suspension shall be extended by one day for each day over ten (10) days respondent is absent from California. During any such period of tolling of suspension, respondent must nonetheless comply with all terms and conditions of probation.

Respondent must notify the board in writing within ten (10) days of departure, and must further notify the board in writing within ten (10) days of return. The failure to provide such notification(s) shall constitute a violation of probation. Upon such departure and return, respondent shall not return to work until notified by the board that the period of suspension has been satisfactorily completed.

~~If respondent leaves California to reside or practice outside this state, or for any period exceeding 10 days (including vacation), respondent must notify the board in writing of the dates of departure and return. Periods of residency or practice outside the state or any absence exceeding a period of 10 days shall not apply to the reduction of the suspension period.~~

~~Respondent shall not act as a pharmacy technician upon returning to this state until notified by the board that the period of suspension has been completed.~~

22. Restitution (Appropriate in cases of drug diversion, theft, fraudulent billing, or patient harm resulting from negligence or incompetence.)

Within _____ days of the effective date of this decision, respondent shall pay restitution to _____ in the amount of $_____. Failure to make restitution by this deadline shall be considered a violation of probation.

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~~EXEMPTEE~~DESIGNATED REPRESENTATIVE

The board files cases against ~~exemptees~~ designated representatives where the violation(s) involve significant misconduct on the part of the licensee. The board believes that revocation is typically the appropriate penalty when grounds for discipline are found to exist. Grounds for discipline include, but are not limited to, the following violation(s) of law(s) involving:

- Possession of dangerous drugs and/or controlled substances
- Use of dangerous drugs and/or controlled substances
- Possession for sale of dangerous drugs and/or controlled substances
- Personal misuse of drugs or alcohol

If revocation is not imposed, the board recommends a minimum ~~of a~~ Category III level of discipline be imposed on the ~~exemptee~~ designated representative. This would include suspension and probation.

~~An exemptee would be required to be reexamined by the board prior to resuming work as an exemptee.~~

TERMS OF PROBATION – ~~EXEMPTEE~~DESIGNATED REPRESENTATIVE

A minimum three-year probation period has been established by the board as appropriate in most cases where probation is imposed. A minimum five-year probation period has been established by the board as appropriate where self-administration or diversion of controlled substances is involved. Terms and conditions are imposed to provide consumer protection and to allow the probationer to demonstrate rehabilitation. A suspension period may also be required as part of the probation order. The board prefers that any stayed order be for revocation rather than for some period of suspension.

Probation conditions are divided into two categories: (1) standard conditions that shall appear in ~~all~~ all probation cases, and (2) optional conditions that depend on the nature and circumstances of a particular case. These conditions may vary depending on the nature of the offense(s).

The board may also impose any other condition appropriate to the case where the condition is not contrary to public policy.

CATEGORY OF VIOLATIONS AND RECOMMENDED PENALTIES

CATEGORY III - Penalty

Minimum: Revocation; Revocation stayed, 90 days actual suspension, three years probation. All standard terms and conditions shall be included and optional terms and conditions as appropriate.

Maximum: Revocation

Applies to all applicable statutes and regulations

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MODEL DISCIPLINARY LANGUAGE – ~~EXEMPTEE~~DESIGNATED REPRESENTATIVE

The following standardized language shall be used in every decision where the order of condition is imposed.

Revocation ~~– Single Cause~~

Designated Representative license ~~Certification~~ number _____, issued to respondent _____ is revoked. Respondent shall relinquish his or her designated representative ~~pocket certification~~ license to the board within ten (10) days of the effective date of this decision. Respondent may not petition the board for reinstatement of his or her revoked ~~certification~~ designated representative license for three (3) years from the effective date of this decision.

~~A condition of reinstatement shall be that the respondent retake the exemption certification examination.~~

Respondent shall pay to the board its costs of investigation and prosecution in the amount of $_____ within fifteen (15) days of the effective date of this decision.

Option: As a condition precedent to ~~Upon~~ reinstatement of his or her revoked designated representative license ~~certification~~ respondent shall reimburse the board for its costs of investigation and prosecution in the amount of $_____. ~~and s~~Said amount shall be paid in full prior to the reinstatement of his or her ~~certification~~ revoked designated representative license, unless otherwise ordered by the board. ~~If the respondent fails to pay the amount specified, his or her certification shall remain revoked.~~

~~Revocation – Multiple Causes~~

~~Certification number _____, issued to respondent _____ is revoked pursuant to Determination of Issues _____, separately and together. Respondent shall relinquish his or her pocket certification to the board within 10 days of the effective date of this decision. Respondent may not petition the board for reinstatement of his or her revoked certification for three years from the effective date of this decision. A condition of reinstatement shall be that the respondent retake the exemption certification examination.~~

~~Respondent shall pay to the board its costs of investigation and prosecution in the amount of $_____ within 15 days of the effective date of this decision.~~

~~**Option:** Upon reinstatement of his or her certification respondent shall reimburse the board for its costs of investigation and prosecution in the amount of $_____, and said amount shall be paid in full prior to the reinstatement of his or her certification. If the respondent fails to pay the amount specified, his or her certification shall remain revoked.~~

Suspension ~~– Single Cause~~

As part of probation, ~~Certification number _____, issued to~~ respondent _____ is suspended from working as a designated representative for _____ beginning the effective

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date of this decision ~~a period of _____~~.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs licensed by the board, or any drug manufacturer, or any other location where dangerous drugs and devices or controlled substances are maintained. Respondent shall not perform any of the duties of a designated representative, nor do any act involving drug selection, selection of stock, manufacturing, dispensing; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices and controlled substances. Respondent shall not resume work until notified by the board.

Respondent shall not direct, control or perform any aspect involving the distribution of dangerous drugs and devices and controlled substances. Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed entity in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

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~~**Suspension - Multiple Causes**~~

~~Certification number _____, issued to respondent is suspended for a period of _____ pursuant to Determination of Issues _____, separately and together. All suspensions shall run concurrently. Respondent is suspended from the duties of an exemptee for _____ beginning the effective date of this decision.~~

Standard Stay/Probation Order

Designated representative license ~~Certification~~ number _____ ~~issued to~~ _____ is revoked; however, the revocation is stayed and respondent is placed on probation for _____ years upon the following terms and conditions:

Issuance of Probationary License (In cases where a Statement of Issues has been filed.)

Upon satisfaction of all statutory and regulatory requirements for issuance of a license, a license shall be issued to respondent and immediately revoked; the order of revocation is stayed and respondent is placed on probation for _____ years upon the following terms and conditions:

Surrender

Respondent surrenders ~~certification~~ designated representative license number _____ as of the effective date of this decision. Respondent shall relinquish his or her ~~pocket certification~~ designated representative license to the board within ten (10) days of the effective date of this decision.

The surrender of respondent's license and the acceptance of the surrendered license by the board shall constitute the imposition of discipline against respondent. This decision constitutes a record of discipline and shall become a part of respondent's license history with the board.

Respondent understands and agrees that if he or she ever files an application for licensure or a petition for reinstatement in the State of California, the board shall treat it as a new application for licensure.

Respondent may not reapply for any ~~certification of~~ license, permit or registration from the board for three (3) years from the effective date of this decision. Respondent stipulates that should he or she ~~respondent~~ apply for any ~~certification~~ license from the board on or after the effective date of this decision, all allegations set forth in the [accusation or petition to revoke probation] shall be deemed to be true, correct and admitted by respondent when the board determines whether to grant or deny the application. Respondent shall satisfy all requirements applicable to that license as of the date the application is submitted to the board prior to issuance of a new license. Respondent is required to report this surrender as disciplinary action. ~~Should respondent apply for any new license, respondent will be subject to all terms and conditions not previously satisfied.~~

~~Respondent shall meet all requirements applicable to that certification as of the date the application is submitted to the board, including, but not limited to exemptee reexamination prior to the issuance of a new registration or certification.~~

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Respondent further stipulates that he or she shall reimburse the board for its costs of investigation and prosecution in the amount of $_____ within _____ days of the effective date of this decision.

Option: Respondent stipulates that should he or she apply for any ~~certification~~ license from the board on or after the effective date of this decision, ~~that~~ investigation and prosecution costs in the amount of $_____ shall be paid to the board prior to issuance of the ~~certification~~ new license.

Public Reprimand

It is hereby ordered that a public reprimand be issued against designated representative license, _____. Respondent is required to report this reprimand as a disciplinary action.

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Adoption of Stipulation

It is understood by respondent that, in deciding whether to adopt this stipulation, the board may receive oral and written communication from its staff and the ~~Attorney General's~~ Office of the Attorney General. Communications pursuant to this paragraph shall not disqualify the board or other persons from future participation in this or any other matter affecting respondent. In the event this settlement is not adopted by the board, the stipulation will not become effective and may not be used for any purpose, except this paragraph, which shall remain in effect.

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STANDARD CONDITIONS – To be included in all probation decisions/orders.

~~Term Number: (Numbers reflect actual term and condition numbers as listed beginning with page _____.)~~

~~1. Certification Prior to Resuming Work~~
~~5.~~1. Obey ~~a~~All Laws
~~6.~~2. Reporting to the Board
~~7.~~3. Interview with the Board
~~5.~~ 4. Cooperation~~e~~ with Board Staff
~~6.~~ 5. Notice to Employers
6. No Being Designated Representative-in-Charge
~~9.~~7. Reimbursement of Board Costs
~~10.~~8. Probation Monitoring Costs
~~15.~~9. Status of License
10. License Surrender While on Probation/Suspension
~~16.~~11. Notification of a Change in Name, Residence Address, ~~Employment~~/Mailing Address or Employment ~~Change~~
~~17.~~12. Tolling of Probation
~~18.~~13. Violation of Probation
~~19.~~14. Completion of Probation
~~14.License Surrender While on Probation/Suspension~~

OPTIONAL CONDITIONS

~~Term Number: (Numbers reflect actual term and condition numbers as listed beginning with page _____.)~~

~~1.Actual Suspension~~
~~2.~~15. No Ownership of Licensed Premises
~~3.~~16. Attend Substance Abuse Recovery Relapse Prevention and Support Groups
~~4.~~17. Random Drug Screening
~~5.~~18. Work Site Monitor
~~6.~~19. Notification of Departure
~~7.~~20. Abstain from Drugs and Alcohol Use
~~8.~~21. Tolling of Suspension
22. Restitution

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STANDARD CONDITIONS - TO BE INCLUDED IN ALL PROBATIONS

~~3.Reexamination Prior to Resuming Work~~

~~Respondent shall be suspended from working as an exemptee until he or she takes and passes the exemption examination as scheduled by the board after the effective date of this decision.~~

~~During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food animal drug retailer or any other distributor of drugs which is licensed by the Board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not do any act involving wholesaling, or repackaging or manufacturing, nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances. Respondent shall not direct or control any aspect of the practice of pharmacy.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any pharmacy or wholesaler in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

~~2.~~1. Obey All Laws

Respondent shall obey all state and federal laws and regulations ~~substantially related to or governing the practice of pharmacy~~.

Respondent shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- an arrest or issuance of a criminal complaint for violation of any state or federal law
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distribution or billing or charging for of any drug, device or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

~~3.~~2. Reporting to the Board

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, ~~R~~respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended

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~~automatically~~ until such time as the final report is made and accepted by the board.

~~4.~~3. Interview with the Board

Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, upon request at ~~various~~such intervals ~~at a~~and locations ~~to be~~as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

~~5.~~4. Cooperation~~e~~ with Board Staff

Respondent shall cooperate with the board's inspectional program and ~~in~~ with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his or her probation. Failure to ~~comply~~ cooperate shall be considered a violation of probation.

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~~6.~~5. Notice to Employers

During the period of probation, Rrespondent shall notify all present and prospective employers of the decision in case number _____ and the terms, conditions and restrictions imposed on respondent by the decision, as follows:~~.~~

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause his or her direct supervisor, designated representative-in-charge (including each new designated representative-in-charge employed during respondent's tenure of employment) and owner ~~employer~~ to report to the board in writing acknowledging that the listed individual(s) has/have ~~employer has~~ read the decision in case number _____ and terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgement(s) to the board.

If respondent works for or is employed by or through a pharmacy employment service, respondent must notify ~~the pharmacist-in-charge~~ his or her direct supervisor, designated representative-in-charge and/~~or~~ owner at ~~every pharmacy~~ each entity licensed by the board of the terms and conditions of the decision in case number _____ in advance of the respondent commencing work at each ~~pharmacy~~ licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy employment service, respondent shall cause his or her direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that he or she has read the decision in case number _____ and the terms and conditions imposed thereby. It shall be the respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgements to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision shall include any full-time, part-time, temporary or relief service or pharmacy management service as a ~~pharmacy technician~~ designated representative or in any position for which a designated representative license is a requirement or criterion for employment, whether the respondent is considered an employee or independent contractor or volunteer.

6. No Being Designated Representative-in-Charge

During the period of probation, respondent shall not be the designated representative-in-charge of any entity licensed by the board unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

7. ~~–~~Reimbursement of Board Costs

As a condition precedent to successful completion of probation, Rrespondent shall pay to the board its costs of investigation and prosecution in the amount of $_____. Respondent shall make said payments as follows: _____. There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the

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deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondent shall not relieve respondent of his or her responsibility to reimburse the board its costs of investigation and prosecution.

~~Option: If respondent fails to make any payment by the directed deadline(s), the stay shall terminate and the license shall be revoked without further notice or opportunity to be heard.~~

8. ~~–~~Probation Monitoring Costs

Respondent shall pay ~~the~~ any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board ~~at the end of each year of probation~~ on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

9. ~~–~~Status of License

Respondent shall, at all times while on probation, maintain an active, current ~~certification~~ designated representative license with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.

If respondent's ~~certification~~ designated representative license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication, respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

10. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent cease work due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his or her designated representative license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the board.

Upon acceptance of the surrender, respondent shall relinquish his or her designated representative license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent may not reapply for any license, permit, or registration from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

~~10.~~11. Notification of a Change in Name, Residence Address, ~~Employment/~~Mailing Address or Employment~~Change~~

Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving and/~~or~~ the address of the new employer,

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supervisor ~~or~~ and owner and work schedule, if known. Respondent shall further notify the board in writing within ten (10) days of a change in name, residence address and mailing address, or phone number.
Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

~~11.~~12. Tolling of Probation

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a designated representative in California for a minimum of _____ hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation.

~~It is a violation of probation for respondent to work less than _____ hours per month as an exemptee.~~ Should respondent, regardless of residency, for any reason (including vacation) cease ~~practicing~~ working as ~~an exemptee~~ designated representative for a minimum of _____ hours in California, respondent must notify the board in writing within ten (10) days of cessation of ~~practice~~ work and must further notify the board in writing within ten (10) days of ~~or~~ the resumption of ~~the practice~~ work. Any failure to provide such notification(s) shall be considered a violation of probation. ~~Such periods of time shall not apply to the reduction of the probation period.~~

It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding ~~three consecutive years~~ thirty-six (36) months.

"Cessation of ~~practice~~work" means any ~~period of time exceeding 30 days~~ calendar month during ~~in~~ which respondent is not ~~engaged in the practice of a pharmacy technician~~ working as a designated representative for at least _____ hours as a designated representative as defined ~~in section _____ of the~~ by Business and Professions Code section 4053 ~~or as an exemptee as defined in section _____ of the Business and Professions Code~~. "Resumption of work" means any calendar month during which respondent is working as a designated representative for at least _____ hours as a designated representative as defined by Business and Professions Code section 4053.

~~12.~~13. Violation of Probation

If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order ~~which~~ that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent

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during probation, the board shall have continuing jurisdiction, and the period of probation shall be automatically extended, until the petition to revoke probation or accusation is heard and decided.

~~If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty which was stayed.~~

~~13.~~14. Completion of Probation

Upon written notice by the board indicating successful completion of probation, respondent's ~~certificate~~ designated representative license will be fully restored.

~~14. License Surrender while on Probation/Suspension~~

~~Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his or her license to the board for surrender. The board shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation.~~

~~Upon acceptance of the surrender, respondent shall relinquish his or her pocket license to the board within 10 days of notification by the board that the surrender is accepted. Respondent may not reapply for any license from the board for three years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.~~

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OPTIONAL CONDITIONS OF PROBATION

~~2. Actual Suspension~~

~~3.~~

~~As part of probation, respondent is suspended from the duties of a pharmacy technician for _____ beginning the effective date of this decision.~~

~~During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not do any act involving drug selection, selection of stock, manufacturing, compounding or dispensing; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any entity licensed by the board in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

~~During suspension, respondent shall not perform any of the duties of a pharmacy technician as provided by Section 1793.2 of the California Code of Regulations.~~

~~2.~~15. No Ownership of Licensed Premises

Respondent shall not own, have any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

Option: Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If respondent currently owns or has any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

~~3.~~16. Attend Substance Abuse Recovery Relapse Prevention and Support Groups

(Appropriate for those cases with chemical dependency (alcohol, drugs))

Within thirty (30) days of the effective date of this decision, respondent shall begin regular attendance at a ~~board-approved~~ recognized and established substance abuse recovery support group in California, (e.g., Alcoholics Anonymous, ~~Cocaine~~ Narcotics Anonymous, etc.,) which has been approved by the board or its designee. Respondent must attend at least one group meeting per week unless otherwise directed by the board or its designee. Respondent shall

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continue regular attendance and submit signed and dated documentation confirming attendance with each quarterly report for the duration of probation. Failure to attend or submit documentation thereof shall be considered a violation of probation.

~~4.~~17. Random Drug Screening (Appropriate for those cases with chemical dependency (alcohol, drugs))

Respondent, at his or her own expense, shall participate in random testing, including but not limited to biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or a ~~other~~ drug screening program ~~approved~~ as directed by the board or its designee. ~~The length of time shall be for the~~ Respondent may be required to participate in testing for the entire probation period and the frequency of testing will be determined by the board or its designee. At all times respondent shall fully cooperate with the board or its designee, and shall, when directed, submit to such tests and samples for the detection of alcohol, narcotics, hypnotics, dangerous drugs or other controlled substances as the board or its designee may direct. Failure to timely submit to testing as directed shall ~~constitute~~ be considered a violation of probation. Upon request of the board or its designee, respondent shall provide documentation from a licensed practitioner that the prescription for a detected drug was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation. Any confirmed positive ~~drug~~ test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment shall be considered a violation of probation and shall result in the ~~immediate~~ automatic suspension of ~~practice~~ work by respondent. Respondent may not resume ~~the practice of pharmacy~~ work as a designated representative until notified by the board in writing.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs licensed by the board, or any drug manufacturer, or any other location where dangerous drugs and devices or controlled substances are maintained. Respondent shall not perform any of the duties of a designated representative, nor do any act involving drug selection, selection of stock, manufacturing, dispensing; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices and controlled substances. Respondent shall not resume work until notified by the board.

Respondent shall not direct, control or perform any aspect involving the distribution of dangerous drugs and devices and controlled substances. Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed entity in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

~~5.~~18. Work Site Monitor (Appropriate for those cases with chemical dependency (alcohol, drugs))

Within ten (10) days of the effective date of this decision, respondent shall identify a work site monitor, for prior approval by the board, who shall be responsible for supervising respondent during working hours. Respondent shall be responsible for ensuring that ~~T~~the work site monitor ~~shall report~~ reports in writing to the board quarterly. Should the designated work site monitor determine at any time during the probationary period that respondent has not maintained sobriety, he or she shall notify the board immediately, either orally or in writing as directed.

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Should respondent change employment, a new work site monitor must be designated, for prior approval by the board, within ten (10) days of commencing new employment. Failure to identify an acceptable initial or replacement work site monitor, or to ensure quarterly reports are submitted to the board, shall be considered a violation of probation.

~~6.~~19. **Notification of Departure** (Appropriate for those cases with chemical dependency (alcohol, drugs))

~~If respondent leaves~~ Prior to leaving the probationary geographic area designated by the board or its designee for a period greater than twenty-four (24) hours, respondent shall notify the board verbally and in writing of the dates of departure and return~~, prior to leaving~~. Failure to comply with this provision shall be considered a violation of probation.

~~7.~~20. **Abstain from Drugs and Alcohol Use** (Appropriate for those cases with chemical dependency (alcohol, drugs))

Respondent shall completely abstain from the possession or use of alcohol, controlled substances, dangerous drugs and their associated paraphernalia except when the drugs are lawfully prescribed by a licensed practitioner as part of a documented medical treatment. Upon request of the board or its designee, respondent shall provide documentation from the licensed practitioner that the prescription for the drug was legitimately issued and is a necessary part of the treatment of the respondent. ~~Respondent shall ensure that he or she is not in the same physical location as individuals who are using illicit substances even if respondent is not personally ingesting the drugs. Additionally, respondent shall cause the prescribing practitioner to notify the board in writing, indicating their awareness of the chemical dependency. Additionally, respondent shall cause the prescribing physician to notify the board in writing, indicating their awareness of the chemical dependency.~~ Failure to timely provide such documentation shall be considered a violation of probation. Respondent shall ensure that he or she is not in the same physical location as individuals who are using illicit substances even if respondent is not personally ingesting the drugs. Any possession or use of alcohol, controlled substances, or their associated paraphernalia not supported by the documentation timely provided, and/or any physical proximity to persons using illicit substances, shall be considered a violation of probation.

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~~8.~~21. **Tolling of Suspension**

During the period of suspension, respondent shall not leave California for any period exceeding ten (10) days, regardless of purpose (including vacation). Any such absence in excess of ten (10) days during suspension shall be considered a violation of probation. Moreover, any absence from California during the period of suspension exceeding ten (10) days shall toll the suspension, i.e., the suspension shall be extended by one day for each day over ten (10) days respondent is absent from California. During any such period of tolling of suspension, respondent must nonetheless comply with all terms and conditions of probation.

Respondent must notify the board in writing within ten (10) days of departure, and must further notify the board in writing within ten (10) days of return. The failure to provide such notification(s) shall constitute a violation of probation. Upon such departure and return, respondent shall not resume work until notified by the board that the period of suspension has been satisfactorily completed.

~~If respondent leaves California to reside or practice outside this state, or for any period exceeding 10 days (including vacation), respondent must notify the board in writing of the dates of departure and return. Periods of residency or practice outside the state or any absence exceeding a period of 10 days shall not apply to the reduction of the suspension period.~~

~~Respondent shall not act as a pharmacy technician upon returning to this state until notified by the board that the period of suspension has been completed.~~

22. **Restitution** (Appropriate in cases of drug diversion, theft, fraudulent billing, or patient harm resulting from negligence or incompetence.)

Within _____ days of the effective date of this decision, respondent shall pay restitution to _____ in the amount of $ _____. Failure to make restitution by this deadline shall be considered a violation of probation.

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TERMS OF PROBATION – PREMISES

A minimum three-year probation period has been established by the board as appropriate in most cases where probation is imposed. A minimum five-year probation period has been established by the board as appropriate where self-administration or diversion of controlled substances ~~is involved~~ has occurred at a licensed premises. Terms and conditions are imposed to provide consumer protection ~~and to allow the probationer to demonstrate rehabilitation~~. A suspension period may also be required as part of the probation order. The board prefers that any stayed order be for revocation rather than for some period of suspension.

Probation conditions are divided into two categories: (1) standard conditions that shall appear in ~~all~~ all probation cases, and (2) optional conditions that depend on the nature and circumstances of a particular case. These conditions may vary depending on the nature of the offense(s).

The board may also impose any other condition appropriate to the case where the condition is not contrary to public policy.

CATEGORIES OF VIOLATIONS AND RECOMMENDED PENALTIES

The California Pharmacy Law ~~specifies the~~identifies offenses for which the board may take disciplinary action against a license. ~~The following are categories of violations used by the board in determining appropriate disciplinary penalties.~~Included among grounds for discipline are violations of the Pharmacy Law itself, violations of regulations promulgated by the board, and violations of other state or federal statutes or regulations.

The following are categories of possible violations used by the board to determine appropriate disciplinary penalties. These categories represent the judgment of the board as to the perceived seriousness of particular offenses.

Under each category, the board has grouped statutes and regulations where violations would typically merit the recommended range of minimum to maximum penalties for that category. These lists are representative, and are not intended to be comprehensive or exclusive. Where a violation not included in these lists is a basis for disciplinary action, the appropriate penalty for that violation may be best derived by comparison to any analogous violation(s) that are included. Where no such analogous violation is listed, the category descriptions may be consulted.

These categories assume a single violation of each listed statute or regulation. For multiple violations, the appropriate penalty shall increase accordingly. Moreover, if an individual has committed violations in more than one category, the minimum and maximum penalties shall be those recommended in the highest category.

The board also has the authority, pursuant to Business and Professions Code section 4301(n), to impose discipline based on disciplinary action taken by another jurisdiction. The discipline imposed by the board will depend on the discipline imposed by the other jurisdiction, the extent of the respondent's compliance with the terms of that discipline, the nature of the conduct for which the discipline was imposed, and other factors set forth in these guidelines.

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CATEGORY I

Minimum: Revocation; Revocation stayed; one-year probation. All standard terms and conditions shall be included and optional terms and conditions as appropriate.

Maximum: Revocation

Category I discipline is recommended for:

- violations which are relatively minor but are potentially harmful
- repeated violations of a relatively minor nature:

Violations of the following codes are ~~as follows~~representative of this category:

BUSINESS AND PROFESSIONS CODE

Article 3. Scope of Practice and Exemptions

4053 Exemptee Supervision~~or~~ of Manufacturers~~,~~ etc.: Requirements~~Wholesalers, and Licensed Laboratories; Veterinary Food-Animal Drug Retailers~~

4054 ~~Supplying Dialysis Drugs~~Supply by Manufacturer, etc. of Certain Dialysis Drugs and Devices

4056 ~~Exempt Hospitals~~Purchase of Drugs at Wholesale – Hospital Containing 100 Beds or Less

4057 ~~Exempt Articles~~Exceptions to Application of this Chapter

4058 ~~License to be Displayed~~Display of Original License

4062 ~~Furnishing Drugs during Emergency~~Furnishing Dangerous Drugs During Emergency

4064 Emergency Refills of Prescription Without Prescriber Authorization

4065 ~~Administration through Injection Card System~~Injection Card System; Requirements for Administration

4066 Furnishing ~~to Ocean~~ Dangerous Drugs to Master or First Officer of Vessel

Article 4. Requirements for Prescription

4070 Reduction of Oral or Electronic Prescription to Writing

4071 Prescriber's May Authorize Agent to Transmitting Prescriptions; Schedule II Excluded

4072 Oral or Electronic ~~Transmitting~~ Transmission of Prescriptions ~~from a~~ - Health Care Facility

4073 Substitution of Generic Drug ~~Product Selection~~- Requirements and Exceptions

4074 Drug ~~Warnings~~Risk: Informing Patient; Providing Consultation for Discharge Medications

4076 Prescription Container - ~~Label~~ Requirements for Labeling

4077 ~~Labeling~~Dispensing Dangerous Drug in Incorrectly Labeled Container

Article 5. Authority of Inspectors

4082 ~~Information about Personnel~~Names of Owners, Managers and Employees Open for Inspection

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Article 6. General Requirements

4100 Change of ~~Name or Address~~ or Name – Notification to Board
~~4102 Skin Puncture for Patient Training~~
4103 Blood Pressure ~~Measurement.~~ Taking by Pharmacist

Article 7. Pharmacies

4114 Intern Pharmacist; Activities Permitted
~~4120Emergency Kit for Licensed Health Care Facilities~~
4119.5 Transferring or Repackaging Dangerous Drugs by Pharmacy
4120 Nonresident Pharmacy: Registration Required
4121 Advertisement for Prescription ~~Price Advertising~~Drug: Requirements; Restrictions
4122 ~~Requests for~~ Required Notice at Availability of Prescription Price Information, General Product Availability, Pharmacy Services; Providing Drug Price Information; Limitations on Price Information Requests
4123 ~~Pharmacy contracts for Compounding of Parenteral Drugs~~Compounding Drug for Other Pharmacy for Parenteral Therapy; Notice to Board
4124 ~~Contact Lens~~ Dispensing Replacement Contact Lenses: Requirements; Patient Warnings; Registration with Medical Board; Application of Section to Nonresident Pharmacies

Article 9. Hypodermic Needles and Syringes

4141 Furnishing Without License ~~Required~~
4142 Prescription Required
4143 Exemption: ~~Wholesale~~ Sales to Other Entity, Physician, etc.
4144 ~~Exemption:~~ Industrial Uses Exception
4145 ~~Exemption: Human (Insulin; Adrenaline) or Animal Use~~Exception: Furnishing for Administration of Insulin, Adrenaline, or Specified Animal Uses; Conditions
~~4146 Hypodermic Register~~
4148 Confiscation if Found Outside Licensed Premises
4149 ~~Nonresident~~ Sale by Distributor

Article 10. Pharmacy Corporations

4151 Licensure Requirements ~~for Shareholders, Directors, and Officers~~
4152 Corporate Name Requirements
4153 Shareholder Income w~~W~~hile Disqualified
4156 Unprofessional Conduct by Corporation

Article 11. Wholesalers and Manufacturers

4161 ~~Out-of-State Manufacturer or~~ Nonresident Wholesaler: When License Required; Application
4162 ~~Registration — Agent~~Issuance or Renewal of Wholesaler License; Surety Bond
4164 ~~Sales to Unauthorized Persons~~Reports Required
4165 Sale or Transfer of Dangerous Drug or Device Into State: Furnishing Records to Authorized Officer on Demand; Citation for Non-compliance
4166 ~~Responsibility until Delivery~~Shipping of Dangerous Drugs or Devices – Wholesaler or Distributor
4167 Wholesaler: Bar on Obtaining Dangerous Drugs or Devices It ~~More Than~~ Cannot Maintain ~~Be Stored~~ on Licensed Premises

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Article 13. Non-Profit or Free Clinics

~~4182License Required (Non-Profit, etc Clinics)~~
~~4183License Requirements~~
4180 Purchase of Drugs at Wholesale Only with License: Eligible Clinics
4181 License Requirements; Policies and Procedures; Who May Dispense
4182 ~~Application~~Duties of Professional Director; Consulting Pharmacist Required
4183 No ~~Medi-Cal~~Professional Dispensing Fee
4184 ~~No Schedule II~~ Dispensing Schedule II Substance Prohibited
4186 ~~Professional Director~~Automated Drug Delivery Systems

Article 14. Surgical Clinics

4190 Purchase of Drugs at Wholesale: Permitted Uses of Drugs; Required Records and Policies; License Required ~~(Surgical Clinic)~~
4191 ~~License~~ Compliance with Department of Health Services Requirements; Who May Dispense Drugs
4192 Duties of Professional Director; Providing Information to Board
4193 ~~No Medi-Cal~~Clinic Not Eligible for Professional Dispensing Fee; Ban on Offering Drugs for Sale
4194 ~~No Schedule II~~ Dispensing of Schedule II Substance by Clinic Prohibited; Physician May Dispense; Administration Authorized in Clinic

Article 15. Veterinary Food-Animal Drug Retailers

4196 License Required;; Temporary License on Transfer of Ownership; Persons Authorized in Storage Area; ~~Security~~
4197 Minimum Standards;; Security; Sanitation; Board Regulations; Waivers
4198 Written Policies and Procedures Required;; Contents; Training of Personnel; Quality Assurance;; Consulting Pharmacist

Article 17. Continuing Education

~~4233Renewal Requirements~~
~~4234Course Content~~
4231 Requirements for Renewal of Pharmacist License; Clock Hours; Exemption for New Licensee
4232 Content of Courses

Article 18. Poisons

4240 Application of Act

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Article 20. Prohibitions and Offenses

4341 ~~Advertising in Compliance with Sections 651.3~~Advertisement of Prescription Drugs or Devices
4343 ~~Use of Sign with "Pharmacy" or Similar Terms~~Buildings: Prohibition Against Use of Certain Signs Unless Licensed Pharmacy Within

CALIFORNIA CODE OF REGULATIONS, TITLE 16

1704 Change of aAddress ~~reporting a change of address~~
1705 Notification of Bankruptcy, Receivership or Liquidation ~~reporting the sale, inventory and location of records of dangerous drugs by a pharmacy, wholesaler or manufacturer in bankruptcy~~
1708.2 Discontinuance of bBusiness ~~notification to board of a discontinuance of business and submission of appropriate forms~~
1708.4 Pharmacist ~~h~~Handling rRadioactive dDrugs ~~training of a nuclear pharmacist~~
1708.5 Pharmacy Furnishing Radioactive Drugs ~~nuclear pharmacy requirements~~
1709 Names of Owners and ~~p~~Pharmacist- in- cCharge ~~required information on a pharmacy permit, reporting PIC and owners on initial and renewal applications, and reporting of corporate officer changes~~
1714 ~~Building~~ Operational Standards and Security
1715.6 Reporting dDrug lLoss ~~reporting loss of controlled substances to the Board within thirty (30) day~~
1716 Variation from pPrescriptions ~~prescription errors, deviation from prescription without consent of prescriber~~
1717 ~~Pharmaceutical~~ Pharmaceutical pPractice ~~dispensing in new containers, pharmacist maintain on prescription record: date and initial of pharmacist, brand name of drug or device and indication if generic and manufacturer name, refill information, orally transmitted prescription requirements, depot of a prescription or a medication, prescription transfers, identification of pharmacist responsible for filling a prescription~~
1717.1 Common Electronic Files ~~establishing a common electronic file to maintain required dispensing information~~
1717.4 Electronic Transmission of Prescriptions ~~transmitting prescriptions by electronic means from prescriber to the pharmacy~~
1718.1 Manufacturer's Expiration Date ~~handling of prescription drugs not bearing a manufacturer's expiration date pursuant to federal law~~
1726 ~~Preceptor~~Supervision of Intern Pharmacists
~~1727 Intern Pharmacist~~
1728 ~~Intern Experience~~—Requirements for ~~Licensure~~Examination
1732.1 Requirements for ~~Recognized~~ Accredited Providers ~~requirements to provide continuing education courses as a recognized provider for California pharmacists~~
1732.3 ~~Coursework Approval for Providers~~Requirements for Continuing Education Courses
1732.4 Provider Audit Requirements

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1732.5 Renewal Requirements for Pharmacist
1744 Drug wWarnings ~~oral or written warnings when a drug should not be taken with alcohol or when a person should not drive~~
~~1751 to 1751.09 and 1751.11 to~~
~~1751.12 Compounding Area for Parenteral Solutions parenteral therapy requirements for pharmacists and pharmacies~~
1751 Sterile Injectable Compounding Area
1751.01 Facility and Equipment Standards for Sterile Injectable Compounding from Non-Sterile Ingredients
1751.02 Policies and Procedures
1751.11 Furnishing to Home Health Agencies and Licensed Hospices
1751.12 Obligations of a Pharmacy Furnishing Portable Containers
1771 Posting of ~~n~~Notice of sSuspension ~~suspended pharmacy must post a notice of suspension~~
1772 Disciplinary cConditions of sSuspension ~~suspended pharmacist shall not enter a pharmacy prescription area or perform pharmacy related duties~~
1780 Minimum sStandards for wWholesalers
1780.1 Minimum Standards for Veterinary Food-Animal Drug Retailers
1781 Exemption cCertificate ~~exemptee must be present in a manufacturer's or wholesaler's licensed premises~~
1786 Exemptions ~~return of exemption certificate to board upon termination of employment~~
1787 Authorization to Distribute Hemodialysis Drugs and Devices
1790 Assembling and Packaging
1791 Labeling
1792 Receipt ~~of~~ for Shipment

HEALTH AND SAFETY CODE, ~~TITLE 22~~

11100 Report of Certain Chemical: Chemicals Included; Exclusions; Penalties ~~controlled substance transaction reporting sales of restricted chemicals to Department of Justice~~
11100.1 Report of Chemicals ~~controlled substances~~ rReceived from oOutside sState; Penalties ~~reporting Purchases of restricted chemicals from outside California~~
~~11124 Inventory of Controlled Substances~~
11151 Limitation on Filling Prescriptions From Medical Students ~~Issued By Unlicensed Person Lawfully Practicing Medicine~~
11158 Prescription ~~r~~Required for Schedule ~~I,~~ II, III, ~~or~~ IV, or V cControlled sSubstances ~~prescriptions for controlled substances must comply with requirements prior to dispensing;~~ Exception for Limited Dispensing, Administration
11159 Chart Order Exemption for pPatient in cCounty or lLicensed ~~h~~Hospital; Maintaining Record for Seven Years ~~controlled substance orders in hospitals~~
11159.1 Chart Order Exemption for Clinic ~~Records~~Patient; Maintaining Record for Seven Years
11159.2 Exception to Triplicate Prescription Requirement ~~Terminally Ill Exception~~
11167 Emergency dDispensing of Schedule II sSubstance; Circumstances and Requirements ~~emergency oral Schedule II prescriptions; must receive a triplicate within seventy two (72) hours~~

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11167.5 ~~Emergency oOral~~ or Electronic pPrescriptions for Schedule II Controlled Substance for Specified iIn-patients, Residents, and Home Hospice Patients: Requirements ~~oral orders for Schedule II drugs in a skilled nursing facility, intermediate care facility, or a home health care agency providing hospice care; pharmacy to obtain special triplicates from Dept. of Justice; facility must forward all signed order to the pharmacy~~

11171 Prescribing, etc. Controlled Substance Only as Authorized~~administering, or furnishing controlled substance – furnishing controlled substances must be consistent with law~~

11172 Antedating or pPostdating pPrescription Prohibited

11175 Prohibition on Obtaining ~~and~~ or pPossessi~~o~~nng nNonconforming pPrescription; Prohibition on oObtaining cControlled sSubstance by nNonconforming pPrescription

11180 Prohibition on Controlled sSubstance oObtained or pPossessed by nNonconforming pPrescription ~~possession of a controlled substance obtained from noncomplying prescriptions~~

11200 Restrictions on dDispensing or rRefilling; Refill of Schedule II Prescription Barred ~~refill restrictions of controlled substances~~

11201 Emergency Refill ~~by Pharmacist~~of Schedule III, IV, or V Prescription; Circumstances; Requirements

11205 Maintenance and rRetention of Records in Separate fFile ~~separate prescription file for Schedule II prescriptions~~

11206 Required iInformation on Prescription ~~information required on a prescription for controlled substances~~

11209 Delivery ~~of Controlled~~and Receiving Requirements for Schedule II, III, and IV Substances; Violation

11210 Issuing Prescription; By Whom; For What Purpose; Quantity to Be Prescribed ~~under authorized project – a prescriber may not prescribe controlled substances to treat addiction~~

11250 Authorized Retail Sale by Pharmacists to Physicians, etc.; Required Order Form

11251 Authorized Wholesale Sale by Pharmacists

11252 Preservation of fFederally rRequired fForms ~~a wholesaler or manufacturer must maintain records of sales~~

11253 Duration of rRetention

11255 Actions cConstituting sSale ~~orders for future delivery constitutes a sale of a controlled substance~~

11256 Required Report of Order bBy or Sale to Out-of-State Wholesaler or Manufacturer

111225 to

111655 Adulterated or Misbranded Drugs or Devices

CODE OF FEDERAL REGULATIONS, TITLE 21

1301.13 ~~Persons Required to Register~~Application for registration; time for application; expiration date; registration for independent activities; application forms, fees, contents and signature; coincident activities.

1301.14 ~~Separate Registration for Separate Locations~~Filing of application; acceptance for filing; defective applications.

1301.71 Security requirements, generally.

1301.72 Physical security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; storage areas.

1301.73 Physical security controls for non-practitioners; compounders for narcotic treatment programs; manufacturing and compounding areas.

1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.

~~3.~~1301.77 ~~Physical s~~Security controls for ~~practitioners~~freight forwarding facilities.

~~2.Other Security Controls for Practitioners~~

1301.90 Employee screening procedures.

1301.91 Employee responsibility to report drug diversion.

1301.92 Illicit activities by employees.

1302.03 Symbol required; exceptions.

1302.04 Location and size of symbol on label and labeling.

1302.05 Effective Ddates of Llabeling Rrequirements.

1302.06 Sealing of controlled substances.

1302.07 Labeling and packaging requirements for imported and exported substances.

~~1304.18 Inventories of importers and exporters~~

1304.11 Inventory requirements.

1304.31 Reports from manufacturers importing ~~opium~~narcotic raw material.

1304.32 Reports of manufacturers importing ~~medicinal~~ coca leaves.

1304.33 Reports to ARCOS.

~~1305.03 to~~

~~1305.06 and~~

~~1305.08 to~~

~~1305.12 and~~

~~1305.14 to~~

~~1305.16 Distributions requiring order forms; persons entitled to obtain and execute order forms; procedure for obtaining order forms; procedure for executing order forms; persons entitled to fill order forms; procedure for filling order forms; procedure for endorsing order forms; unaccepted and defective order forms; lost and stolen order forms; return of unused order forms~~

1305.03 Distributions requiring a Form 222 or a digitally signed electronic order.

1305.04 Persons entitled to order Schedule I and II controlled substances.

1305.05 Power of attorney.

1305.06 Persons entitled to fill orders for Schedule I and II controlled substances.

1305.11 Procedure for obtaining DEA Forms 222.

1305.12 Procedure for executing DEA Forms 222.

1305.14 Procedure for endorsing DEA Forms 222.

1305.15 Unaccepted and defective DEA Forms 222.

1305.16 Lost and stolen DEA Forms 222.

1306.03 Persons entitled to issue prescriptions.

1306.05 Manner of issuance of prescriptions.

1306.14 Labeling of substances and filling of prescriptions. ~~Schedule II.~~

1306.24 Labeling of substances and filing of prescriptions. ~~Schedule III and IV~~

~~4.Transfer of Schedule III, IV, and V Prescriptions~~

1306.25 Transfer between pharmacies of prescription information for Schedules III, IV, and V controlled substances for refill purposes.

1306.26 Dispensing ~~W~~without a ~~P~~prescription.

1307.11 Distribution by dispenser to another practitioner or reverse distributor.

1307.12 ~~Manufacture and d~~Distribution ~~of narcotic solutions and compounds by a pharmacist~~to supplier or manufacturer.

1307.13 ~~Distribution to supplier~~Incidental manufacture of controlled substances.

1307.21 Procedure for disposaling of controlled substances.

1700.1 to

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1707.15 Child-resistant containers.

~~MISCELLANEOUS - HEALTH AND SAFETY CODE,TITLE 22~~

~~111225 to~~
~~111655 Adulterated or misbranded drugs or devices~~

~~MISCELLANEOUS-FEDERAL REGULATIONS~~

~~16 CFR 1700.1 to~~
~~1707.15 Child-resistant containers~~

CATEGORY II

Minimum: Revocation; Revocation stayed, three years probation (five years probation where self-administration or diversion of controlled substances ~~is involved~~ occurred at the licensed premises). All standard terms and conditions shall be included and optional terms and conditions as appropriate.

Maximum: Revocation

Category II discipline is recommended for:

- violations with a serious potential for harm
- violations which involve greater disregard for pharmacy law and public safety
- violations which reflect on ethics, care exercised or competence or a criminal conviction not involving dangerous drugs or controlled substances or involving possession or use of dangerous drugs or controlled substances.

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Violations of the following codes are ~~as follows~~representative of this category:

BUSINESS AND PROFESSIONS CODE

650 Rebates or Discounts for Referral Prohibited
650.1 Lease Prohibition – Hospitals or Prescribers
651 Professional Advertising Requirements

Article 3. Scope of Practice and Exemptions

4051(b) Conduct Authorized by Pharmacist ~~from Outside Pharmacy~~
4052 ~~conduct Authorized by Pharmacist~~Furnishing to Prescriber; Permissible Procedures by Pharmacist in Health Care Facility or Clinic or for Other Health Care Provider
4060 ~~Possession of~~ Controlled Substance – Prescription Required; Exceptions
4061 Distribution of ~~Sample~~ Drugs as Sample; Written Request Required
4064 Emergency Refills of Prescription Without Prescriber Authorization
4067 Internet; ~~Prescription~~ Dispensing ~~over the Internet~~Dangerous Drugs or Devices without Prescription
~~1794Proof of Identity of Recipient for Controlled Substance Prescriptions~~
~~1306False or Misleading Labeling~~
4075 Proof of Identity Required – Oral or Electronic Prescription
4078 False or Misleading Label on Prescription

Article 6. General Requirements

4101 ~~Termination as~~ Pharmacist in Charge, Exemptee: Termination of Employment; ~~Notice~~ Notification to Board
~~4106Licensed Employee:Theft or Impairment~~
~~4107Retaining Records on Premises~~
4104 Licensed Employee, Theft or Impairment: Pharmacy Procedures
4105 Retaining Records of Dangerous Drugs and Devices on Licensed Premises; Temporary Removal; Waivers; Access to Electronically Maintained Records

Article 7. Pharmacies

~~4121Non-Resident Pharmacy Registration~~
4112 Nonresident Pharmacy: Registration; Provision of Information to Board; Maintaining Records; Patient Consultation
4113 Pharmacist in Charge; Notification to Board; Responsibilities
4115 Pharmacy Technician: Activities Permitted; Required Supervision; Activities Limited to Pharmacist; Registration; Requirements for Registration; Ratios
~~4117Pharmacy Technician Activities~~
4115.5 Pharmacy Technician Trainee; Placement; Supervision; Requirements
4116 Security of Dangerous Drugs and Devices in ~~—~~Pharmacy; Pharmacist Responsibility for Individuals on Premises; Regulations
4117 ~~Security — Hospital Pharmacy~~Admission to Area Where Narcotics are Stored, etc. – Who May Enter
4120 Non-Rresident Pharmacy; Registration Required
4125 Pharmacy Quality Assurance Program Required; Records Considered Peer Review Documents

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Article 9. Hypodermic Needle and Syringes

4140 Unlawful Possession
4147 Disposal of Needle or Syringe

Article 11. Wholesalers and Manufacturers

4161 Nonresident Wholesaler: When License Required; Application
4163 ~~Sales to~~ Unauthorized ~~Persons~~Furnishing by Manufacturer or Wholesale
4164 ~~Reporting by Manufacturer and Wholesalers~~Reports Required
4169(a)(1) Prohibited Acts

Article 13. Non-Profit of Free Clinics

4185 Inspections Permitted

Article 14. Surgical Clinics

4195 Inspections Permitted

Article 19. Disciplinary Proceedings

4301 ~~General u~~Unprofessional ~~c~~Conduct ~~and~~ subsections (a)-(h), (j), and (l) ~~through~~ (q)
4302 ~~Pharmacy Corporation~~Discipline of Corporate Licensee for Conduct of Officer, Director, Shareholder
4303 Nonresident Pharmacy; Grounds for Discipline
4304 Out-of-~~S~~state Distributor; ~~s~~ Authority to Discipline
~~4307Failure to Notify Board of Termination of Pharmacist in Charge; Operation of Pharmacy without a Pharmacist~~
4305 Disciplinary Grounds: Failure of Pharmacy, Pharmacist to Notify Board of Termination of Pharmacist in Charge; Continuing to Operate Without Pharmacist
4305.5 Disciplinary Grounds: Failure of Other Entity Licensed by Board, ~~of to Keep~~ Pharmacist ~~in Charge~~ or Exemptee ~~in Charge; Failure~~ to Notify Board of Termination of ~~Same~~Pharmacist in Charge or Exemptee; Continuing to Operate Without Pharmacist or Exemptee
~~4308Violation of Moscone Knox Professional Corporation Act~~
4306 Violation of Professional Corporation Act as Unprofessional Conduct
4306.5 ~~Pharmacist~~ Misuse of Education, etc. by Pharmacist Outside Course of Practice of Pharmacy as Unprofessional Conduct

Article 20. Prohibitions and Offenses

4326 ~~Hypodermics: Obtaining Falsely; Misuse~~Misdemeanor: Obtaining Needle or Syringe by Fraud, etc.; Unlawful Use of Needle or Syringe Obtained from Another
4328 ~~Allowing Compounding by Non-pharmacist~~Misdemeanor: Permitting Compounding, Dispensing, or Furnishing by Non-pharmacist
4330 ~~Pharmacy; Failure to Place Pharmacist in Charge , Subverting Compliance with Law by Pharmacist in Charge~~Misdemeanor: Non-pharmacist Owner Failing to Place Pharmacist in Charge, Dispensing or Compounding Except by Pharmacist, Interfering with Pharmacist in Charge
4331 ~~Veterinary Food-Animal Drug Retailer; Dispensing by Other than Pharmacist or Exemptee; Failure to Place Pharmacist or Exemptee in Charge~~Misdemeanor: Medical Device Retailer, Wholesaler, Veterinary Food-Animal Drug Retailer Failing to Place Pharmacist or Exemptee in Charge, Permitting Dispensing or Compounding Except by Pharmacist or Exemptee
4333 ~~Failure to Maintain Prescription Files~~Maintaining Prescriptions, Other Drug Records on Premises, Open to Inspection; Waiver; Willful Failure to Keep or Permit Inspection of Records of Prescriptions, Other Records as Misdemeanor
4340 ~~Advertisement of Pharmacy Services by Unregistered Non-Resident Pharmacy~~Unlawful Advertising by Nonresident Pharmacy Not Registered with Board

Article 22. Unfair Trade Practices

4380 Resale of Preferentially Priced Drugs; ~~; Emergency~~ Prohibition; Exceptions
~~4381 Violation of Section 4380 as Unfair Competition; Right of Private Action to Enforce~~
4382 ~~Authority of~~ Board ~~to~~ May Audit ~~for Compliance~~Sales to Walk-in Customers

CALIFORNIA CODE OF REGULATIONS, TITLE 16

1707.1 Duty to ~~m~~Maintain ~~m~~Medication ~~p~~Profiles (~~p~~Patient ~~m~~Medication ~~r~~Records) ~~requirements for maintenance of patient medication profiles~~
1707.2 Notice to ~~c~~Consumers and ~~d~~Duty to ~~c~~Consult ~~requirements of pharmacist to consult; posting of notice to consumers~~
1707.3 ~~Reviewing the patient profile prior to consultation~~Duty to Review Drug Therapy and Patient Medication Record Prior to Deliver
1709.1 Designation of ~~p~~Pharmacist in ~~c~~Charge
1714.1 Pharmacy Operation ~~d~~During Temporary Absence of a Pharmacist
~~1721Self-Assessment of a Pharmacy by the Pharmacist-in-Charge~~
1715 Self-Assessment of a Pharmacy by the Pharmacist-in-Charge
1715.5 ~~Transmitting Schedule II Prescription Information to CURES~~Implementation of Electronic Monitoring of Schedule II Prescriptions
1716.1 Compounding Unapproved ~~d~~Drugs for ~~p~~Prescriber ~~o~~Office ~~u~~Use
1716.2 Record ~~r~~Requirements ~~when c~~Compounding for ~~f~~Future ~~f~~Furnishing
1717.2 Notice of Electronic Prescription Files
1717.3 Preprinted, ~~m~~Multiple ~~c~~Check-off ~~p~~Prescription ~~b~~Blanks
1723.1 Confidentiality of Examination Questions
1745 Partial ~~f~~Filling of Schedule II ~~p~~Prescriptions
1751.10 Furnishing to ~~p~~Parenteral ~~p~~Patient at ~~h~~Home ~~carrying and furnishing dangerous drugs to parenteral patients~~
1761(a) Erroneous or Uncertain Prescriptions
1764 Unauthorized ~~d~~Disclosure of ~~p~~Prescriptions ~~revealing the contents of a prescription to unauthorized persons~~
1765 Commissions, ~~g~~Gratuities, and ~~r~~Rebates ~~commission, gratuity or rebate to a health care facility~~
1766 False or ~~m~~Misleading ~~a~~Advertising
1775.3 Compliance with Orders of Abatement
1782 Reporting Sales of Drugs Subject to Abuse

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1783 Manufacturer or Wholesaler Furnishing Drugs or Devices
~~1775.4Compliance with Orders of Abatement~~
~~1784Reporting Sales of Drugs Subject to Abuse~~
~~1785Manufacturer or Wholesaler Furnishing~~
~~1793.1 to~~
~~1793.7 Ancillary personnel - pharmacy technician requirements and tasks~~
1793.1 Duties of a Pharmacist
1793.2 Duties of a Pharmacy Technician
1793.3 Other Non-Licensed Pharmacy Personnel
1793.4 Qualifications for Registration as a Pharmacy Technician
1793.7 Requirements for Pharmacies Employing Pharmacy Technicians
1793.8 Technicians in Hospitals with Clinical Pharmacy Programs

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HEALTH AND SAFETY CODE, ~~TITLE 22~~

11103 Report of ~~t~~Theft, ~~l~~Loss, or ~~s~~Shipping ~~d~~Discrepancy ~~reporting losses of restricted chemicals to Department of Justice~~
~~11123 Warehouseman License~~
~~11124 Warehouse Inventory~~
~~11125 Warehouseman Bond~~
~~11128 Nontransferability of Warehouse License~~
~~11129 Discipline or Denial of Warehouse License~~
~~11130 Disciplinary Grounds for Warehouse License~~
~~11131 Disciplinary Grounds for Warehouse License~~
11150 ~~Issuing Controlled Substance Prescription~~Persons Authorized to Write or Issue a Prescription
11152 Nonconforming ~~p~~Prescriptions Prohibited ~~filling a prescription that does not conform to the requirements of the code~~
11154 ~~Issuing~~ Prescriptions, etc. Must Be for Treatment; Knowing Soliciting of Unlawful Prescription, etc.
11156 Prescribing, etc. ~~Administering or dispensing c~~Controlled ~~s~~Substances to ~~a~~Addict Only as Authorized ~~prohibition on administering or dispensing a controlled substance to an addict or a habitual user~~
11164 ~~Completion of p~~Prescriptions for Schedule II, III, IV and ~~-~~V ~~c~~Controlled ~~s~~Substance; Form and Content; Record of Practitioner Dispensing Schedule II Controlled Substance ~~prescription requirements for controlled substances~~
11165(d) CURES Transmission
11166 Time Limit ~~F~~for Filling Schedule II Prescriptions~~;~~ Knowingly Filling Mutilated, Forged, or Altered Prescriptions Prohibited
11170 Prohibition on Prescribing, etc. ~~c~~Controlled ~~s~~Substance for ~~s~~Self ~~use prohibition on prescribing, administering or furnishing controlled substance to self~~
11179 Retention of Controlled Substance Prescription ~~period prescription file to be maintained for three (3) years~~
11207 ~~Filling prescription o~~Only ~~by p~~Pharmacist or ~~i~~Intern Authorized to Fill Prescription ~~pharmacist dispensing, compounding, filling by pharmacist or intern pharmacist only~~
11209 Delivery and Receiving Requirements for Schedule II, III, and ~~&~~ IV Substances; Violation
11350 Possession of ~~s~~Specified ~~c~~Controlled ~~s~~Substance ~~illegal possession of a narcotic~~
11377 Unlawful ~~p~~Possession of ~~s~~Specified ~~s~~Substance ~~illegal possession of a non-narcotic controlled substance~~

CODE OF FEDERAL REGULATIONS, TITLE 21

1304.03 Persons required to keep records and file reports.
1304.04 Maintenance of records and inventories.
1304.11 ~~General~~ Inventory requirements~~, for inventories~~
1304.21 General requirements for continuing records.
1304.22 Records for manufacturers, distributors, dispensers, researchers, importers and exporters.
1305.07 ~~Power of attorney~~Special procedures for filling certain orders.
1305.13 ~~Preservation of order forms~~Procedure for filling DEA Forms 222.
1306.04 Purpose of issue of prescription.

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1306.06 Persons entitled to fill prescriptions.
~~1306.08Administering or dispensing of narcotic drugs~~
1306.11 ~~–~~Requirement ~~of Schedule II P~~prescriptions.
1306.12 Refilling prescriptions. ~~—Schedule II~~
1306.13 Partial filling of prescriptions. ~~—Schedule II~~
1306.21 Requirement of prescription. ~~—Schedule III and IV~~
1306.22 Refilling of prescriptions. ~~—Schedule III and IV~~
1306.23 Partial filling of prescriptions. ~~—Schedule III and IV~~

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CATEGORY III

Minimum: Revocation; Revocation stayed, 90 days actual suspension, three to five years probation (five years probation where self-administration or diversion of controlled substances ~~is involved~~ occurred at the licensed premises). All standard terms and conditions and optional terms and conditions as appropriate.

For a licensed premises, a minimum 14-28 days actual suspension.

Maximum: Revocation

Category III discipline is recommended for:

- ~~[illegible]~~ most criminal convictions involving dangerous drugs or controlled substances
- ~~[illegible]~~ knowing or willfully violating laws or regulations pertaining to dispensing or distributing dangerous drugs or controlled substances
- ~~[illegible]~~ fraudulent acts committed in connection with the licensee's practice
- ~~[illegible]~~ drug shortages
- ~~[illegible]~~ violation of a licensee's corresponding responsibility.

Violations of the following codes are ~~as follows~~representative of this category:

BUSINESS AND PROFESSIONS CODE

Article 3. Scope of Practice and Exemptions

4051(a) Conduct Limited ~~T~~to Pharmacist
~~4060Furnishing without prescription~~
4059 Furnishing Dangerous Drugs or Devices Prohibited Without Prescription; Exceptions
4059.5 ~~Ordering~~ Who May Order Dangerous Drugs or Devices; Exceptions

Article 5. Authority of Inspectors

4080 Stock of Dangerous Drugs and Devices Kept Open for Inspection
4081 Records of ~~Acquisition and Dispensing;~~ Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory
4085(a) Unlawful to Remove, Sell, Dispose of Embargoed Dangerous Drug or Dangerous Device

Article 7. Pharmacies

4110 ~~Requirement of~~ License Required; Temporary ~~Licenses~~Permit Upon Transfer of Ownership
4111 Restrictions on Prescriber Ownership ~~by Prescribers Prohibited~~

Article 11. Wholesalers and Manufacturers

4169(a)(2) to
4169(a)(5) Prohibited Acts

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Article 15. Veterinary Food-Animal Retailers

4199 Labeling; ~~Recordkeeping~~ Requirements; Maintaining Prescription Records

Article 19. DisciplinaryProceedings

4301 Unprofessional Conduct - ~~S~~subsections (i) ~~and~~ (k) and (o)
4307 Prohibition ~~against of~~ Association ~~with a~~of Individual with Entity License by Board: Length of Prohibition; Individuals Covered; Imposition of Prohibition Through Administrative Act Proceeding
4308 ~~Notification of Licensee Person is~~ Prohibited ~~from~~ Association; ~~Replacement~~Notification of Affected Licensees Known to Board

Article 20. Prohibitions and Offenses

4322 Misdemeanor or Infraction: False Representations to ~~Obtain~~Secure License for Self or Others; False Representation of Licensure; Penalties
4323 Misdemeanor: False Representation of Self as Physician, Agent of Physician, etc. ~~by Telephone or Electronic Transmission to~~ Obtain ~~a~~ Drug
4324 Felony or Misdemeanor: Forgery of Prescription; Possession of Drugs Obtained Through Forged Prescription~~or Alteration~~
4325 Misdemeanor: Manufacture, Possession, etc. of False ~~Producing~~ Prescription Blanks ~~Without Authorization~~
4327 Misdemeanor: Sale, Dispensing, or Compounding While Under the Influence ~~Use of Alcohol or~~ Drugs ~~while on Duty~~or Alcoholic Beverages
4329 Misdemeanor: Non-pharmacist ~~Taking Charge~~Acting as Manager, Compounding, Dispensing or Furnishing Drugs
4332 Misdemeanor: Failure or Refusal to Maintain or Produce ~~or Provide~~ Required Drug or Device Records; Willful Production of False Records
4335 Voided License: Knowing Failure to Arrange for Disposition of Stock as Misdemeanor
4336 Felony: Knowing or Willful Use of Minor to Violate Specified Sections of Pharmacy Law: Exception for Pharmacist Furnishing Pursuant to a Prescription
~~4052Failure to Arrange for Transfer of Stock after Closure~~
~~4053Use of Minor as Agent to Violate Pharmacy Law~~

Article 22. Unfair Trade Practices

4380 Resale of Preferentially Priced Drugs: Prohibition; Exceptions

CALIFORNIA CODE OF REGULATIONS, TITLE 16

1718 Current ~~i~~Inventory ~~d~~Defined ~~audit accountability of dangerous drugs~~
1761(b) ~~Controlled substance prescription professional judgment~~Erroneous or Uncertain Prescriptions
~~1771 to~~
~~1774 Disciplinary conditions of suspension and probation~~
1771 Posting of Notice of Suspension
1772 Disciplinary Condition of Suspension

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1773 Disciplinary Conditions of Probation of Pharmacist
1774 Disciplinary Conditions of Probation of Permit

HEALTH AND SAFETY CODE, ~~TITLE 22~~

11104 Providing Chemical for Illicit Manufacturing; Evasion of Reporting Requirements; Penalties~~controlled substances for manufacturing~~
11105 False Statement in Report
~~11122 Storage of Controlled Substances~~
11150 Persons ~~a~~Authorized to ~~w~~Write or ~~i~~Issue a ~~p~~Prescription
11153 Responsibility for Legitimacy of~~controlled substance~~ ~~p~~Prescription; Corresponding Responsibility of Pharmacist ~~corresponding responsibility of a pharmacist~~
11153.5 Wholesaler or Manufacturer Furnishing ~~a c~~Controlled ~~s~~Substance ~~for o~~Other ~~t~~Than ~~for a l~~Legitimate ~~m~~Medical ~~p~~Purpose; Knowing Violation; Factors in Assessing Legitimacy ~~corresponding responsibility of a wholesaler or manufacturer~~
11157 No False or ~~f~~Fictitious ~~p~~Prescriptions ~~issuing a false or fictitious prescription~~
11162.5 Counterfeiting or ~~p~~Possession of ~~c~~Counterfeit Triplicate ~~p~~Prescription ~~b~~Blank; Penalty
11167.5 Pharmacy Generated Prescription for Schedule II Controlled Substance in a Skilled Nursing Facility
11173 Fraud, ~~d~~Deceit, ~~m~~Misrepresentation or ~~f~~False ~~s~~Statement; False Representation; False Label ~~obtaining controlled Substances by fraud or deceit~~
11174 Prohibition on Providing False ~~n~~Name or ~~a~~Address in Connection with Prescription, etc. ~~false name or address on prescription~~
11351 Possession or ~~p~~Purchase for ~~s~~Sale of ~~s~~Specified ~~c~~Controlled ~~s~~Substance ~~illegal possession for sale of a narcotic~~
11368 Forged or ~~a~~Altered ~~p~~Prescriptions ~~forging a narcotic prescription~~
11375 Possession for ~~s~~Sale or ~~s~~Selling ~~s~~Specified ~~s~~Substance
11378 Possession for ~~s~~Sale ~~illegal possession for sale of a nonnarcotic~~
11550 Use~~i~~ng or ~~b~~Being ~~u~~Under ~~t~~he ~~i~~Influence of ~~c~~Controlled ~~s~~Substance
111295 Manufacturing, Selling or Offering for Sale an Adulterated Drug or Device
111300 Unlawful to Adulterate a Drug
111305 Unlawful to Receive in Commerce an Adulterated Drug
111440 Unlawful Manufacturer, selling a misbranded Drug
111445 Unlawful for a Person to Misbrand
111450 Unlawful to Receive into Commerce a Drug that is Misbranded

CATEGORY IV

Penalty: Revocation

Revocation is recommended for violations of the Uniform Controlled Substance Act (Heath and Safety Code 11000 et seq.) involving:

- possession for sale
- transportation
- importation
- sale
- use of a minor for the unlawful sale of controlled substances

Revocation is also recommended when:

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- ~~(3)~~ a respondent fails to file a notice of defense or to appear at a disciplinary hearing where the board has requested revocation in the accusation
- ~~(4)~~ a respondent violates the terms and conditions of probation from a previous disciplinary order
- ~~(5)~~ prior discipline has been imposed, as progressive discipline unless the respondent can demonstrate satisfactory evidence of rehabilitation.

Violations of the following codes are ~~as follows~~representative of this category:

HEALTH AND SAFETY CODE~~, TITLE 22~~

11352	Importing, sSelling, fFurnishing cControlled sSubstance~~—illegal sale of a narcotic~~
11353	Adult iInducing ~~m~~Minor to vViolate ~~controlled substances p~~Provisions
11379	Transporting, iImporting, sSelling cControlled sSubstances~~—illegal sale of a non-narcotic~~
11380	Adult uUsing, sSoliciting or iIntimidating ~~m~~Minor for vViolation~~—violation of non-narcotic provisions or the use of a minor~~

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MODEL DISCIPLINARY LANGUAGE - PREMISES

The following standardized language shall be used in every decision where the order or condition is imposed.

Revocation ~~- Single Cause~~

License number _____, issued to respondent _____, is revoked.

~~For premises:~~ Respondent owner shall, by the effective date of this decision, arrange for the destruction of, the transfer to, sale of or storage in a facility licensed by the board of all controlled substances and dangerous drugs and devices. Respondent owner shall provide written proof of such disposition, submit a completed Discontinuance of Business form and return the wall and renewal license to the board within five days of disposition.

Respondent owner shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent owner shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

~~Revocation - Multiple Causes~~

~~License number _____, issue to respondent _____ is revoked pursuant to Determination of Issues _____, separately and together.~~

~~For premises: Respondent shall, by the effective date of this decision, arrange for the destruction of, the transfer to, sale of or storage in a facility licensed by the board of all controlled substances and dangerous drugs and devices. Respondent shall provide written proof of such disposition to the board within five days of disposition.~~

Suspension ~~- Single Cause~~

License number _____, issued to respondent _____ is suspended for a period of _____ days beginning the effective of this decision.

Respondent shall cease all pharmacy operations during the period of suspension. Failure to comply with this suspension shall be considered a violation of probation.

~~Suspension - Multiple Causes~~

~~Respondent is suspended from _____ operations for _____ beginning the effective date of this decision.~~

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Standard Stay/Probation Order

License number _____, issued to respondent is revoked~~_____~~; however, the revocation~~_____~~ is stayed and respondent is placed on probation for _____ years upon the following terms and conditions:

Issuance of Probationary License (In cases where a Statement of Issues has been filed.)

~~The application for licensure of respondent is hereby granted, on the following terms and conditions:~~

~~3.That, respondent first meet all statutory and regulatory requirements for the issuance of a license to _____.~~

~~2.That, following the satisfaction of #1, respondent's license be issued and immediately revoked, the order of revocation being stayed and respondent placed on probation for a period of _____ years on the following terms and conditions:~~

Upon satisfaction of all statutory and regulatory requirements for issuance of a license, a license shall be issued to respondent and immediately revoked; the order of revocation is stayed and respondent is placed on probation for _____ years upon the following terms and conditions:

Surrender

Respondent owner surrenders license number _____ as of the effective date of this decision. Respondent owner shall relinquish ~~his or her~~the premises wall license and ~~pocket~~ renewal license to the board within ten (10) days of the effective date of this decision.

The surrender of respondent's license and the acceptance of the surrendered license by the board shall constitute the imposition of discipline against respondent. This decision constitutes a record of discipline and shall become a part of respondent's license history with the board.

Respondent owner shall, within ten (10) days of the effective date, arrange for the destruction of, the transfer to, sale of or storage in a facility licensed by the board of all controlled substances and dangerous drugs and devices. Respondent owner shall further provide written proof of such disposition and submit a completed Discontinuance of Business form according to board guidelines.

Respondent owner shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent owner shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Respondent owner understands and agrees that if he or she ever files an application for a licensed premises or a petition for reinstatement in the State of California, the board shall treat it as a new application for licensure.

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Respondent owner may not reapply for any license~~, permit, or registration~~ from the board for three (3) years from the effective date of this decision. Respondent owner stipulates that should he or she apply for any license from the board on or after the effective date of this decision, all allegations set forth in the [accusation or petition to revoke probation] shall be deemed to be true, correct and admitted by respondent when the board determines whether to grant or deny the application. Respondent shall satisfy all requirements applicable to that license as of the date the application is submitted to the board~~, including, but not limited to taking and passing the California Pharmacist Licensure Examination prior to the issuance of a new license~~. Respondent is ~~obligated~~ required to report this surrender as disciplinary action.

Respondent owner further stipulates that he or she shall reimburse the board for its costs of investigation and prosecution in the amount of $_____ within _____ days of the effective date of this decision.

Option: Respondent owner stipulates that should he or she apply for any license from the board on or after the effective date of this decision the investigation and prosecution costs in the amount of $_____ shall be paid to the board prior to issuance of the new license.

Public Reprimand

It is hereby ordered that a public reprimand be issued against licensee, _____. Respondent owner is required to report this reprimand as a disciplinary action.

Adoption of Stipulation

It is understood by respondent owner that, in deciding whether to adopt this stipulation, the board may receive oral and written communication from its staff and the Attorney General's Office. Communications pursuant to this paragraph shall not disqualify the board or other persons from future participation in this or any other matter affecting respondent. In the event this settlement is not adopted by the board, the stipulation will not become effective and may not be used for any purpose, except this paragraph, which shall remain in effect.

Deletions to the regulatory text are indicated by double strike-through, thus: ~~deleted language~~. Additions to the regulatory text are indicated by a double underline, thus: added language

STANDARD CONDITIONS - To be included in all probation decisions/orders.

~~Term Number: (Numbers reflect actual term and condition numbers as listed beginning with page _____.)~~

1. Obey aAll laws
2. Reporting to the Board
3. Interview with the Board
4. Cooperatione with Board Staff
5. Reimbursement of Board Costs
6. Probation Monitoring Costs
7. Status of License
8. License Surrender wWhile on Probation/Suspension
9. Notice to Employees
10. Owners and Officers: Knowledge of the lLaw
11. Posted Notice of Probation

~~11.~~12. Violation of Probation

~~12.~~ 13. Completion of Probation

OPTIONAL CONDITIONS

~~Term Number: (Numbers reflect actual term and condition numbers as listed beginning with page _____.)~~

~~1.Actual Suspension~~

~~2.~~14. Community Services Program

~~3.~~15. Restitution

~~4.~~16. Separate File of Records

~~5.~~17. Report of Controlled Substances

~~6.~~18. Surrender of DEA Permit

~~7.~~19. Posted Notice of Suspension

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STANDARD CONDITIONS: TO BE INCLUDED IN ALL PROBATIONS

~~1.~~1. Obey All Laws

Respondent owner shall obey all state and federal laws and regulations ~~substantially related to or governing the practice of pharmacy~~.

Respondent owner shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- discipline, citation, or other administrative action filed by any state ~~and~~ or federal agency which involves respondent's _____ license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributieng, ~~or~~ billing, or charging for ~~of~~ any drug, device or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

~~2.~~2. Reporting to the Board

Respondent owner shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, Rrespondent owner shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, iIf the final probation report ~~is not~~ is not made as directed, probation shall be automatically extended ~~automatically~~ until such time as the final report is made and accepted by the board.

~~3.~~3. Interview with the Board

Upon receipt of reasonable prior notice, respondent owner shall appear in person for interviews with the board or its designee, ~~upon request at various~~such intervals ~~at a~~and locations ~~to be as~~ are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

~~4.~~4. Cooperatione with Board Staff

Respondent owner shall cooperate with the board's inspectional program and ~~in~~ with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his or her probation. Failure to ~~comply~~ cooperate shall be considered a violation of probation.

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~~5.~~5. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, ~~R~~respondent owner shall pay to the board its costs of investigation and prosecution in the amount of $_____. Respondent owner shall make said payments as follows: _____. There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondent owner shall not relieve respondent of his or her responsibility to reimburse the board its costs of investigation and prosecution.

~~Option: If respondent owner fails to make any payment by the directed deadline(s), the stay shall terminate and the license shall be revoked without further notice or opportunity to be heard.~~

~~6.~~6. Probation Monitoring Costs

Respondent owner shall pay ~~the~~ any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board ~~at the end of each year of probation~~ on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

~~7.~~7. Status of License

Respondent owner shall, at all times while on probation, maintain ~~a~~ current licensure with the board. If respondent owner submits an application to the board, and the application is approved, for a change of location, change of permit or change of ownership, the board shall retain continuing jurisdiction over the license, and the respondent shall remain on probation as determined by the board. Failure to maintain current licensure shall be considered a violation of probation.

If respondent license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

~~8.~~8. License Surrender w~~W~~hile on Probation/Suspension

Following the effective date of this decision, should respondent ~~cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation~~owner discontinue business, respondent owner may tender ~~his or her~~ the premises license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation.

Upon acceptance of the surrender, respondent owner shall relinquish ~~his or her pocket~~ the premises wall and renewal license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent owner shall further submit a completed Discontinuance of Business form according to board guidelines and shall notify the board of the records inventory transfer.

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Respondent owner shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent owner shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Respondent owner may not ~~re~~apply for any ~~license~~ new licensure from the board for three (3) years from the effective date of the surrender. Respondent owner shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

Respondent owner further stipulates that he or she shall reimburse the board for its costs of investigation and prosecution prior to the acceptance of the surrender.

~~9.~~9. Notice to Employees

Respondent owner shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent owner shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, respondent owner shall submit written notification to the board, within fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to submit such notification to the board shall be considered a violation of probation.

"Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

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~~10.~~10. Owners and Officers: Knowledge of the Law

Respondent shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in respondent or respondent's stock, and any officer, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

11. Posted Notice of Probation

Respondent owner shall prominently post a probation notice provided by the board in a place conspicuous and readable to the public. The probation notice shall remain posted during the entire period of probation.

Respondent owner shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

Failure to post such notice shall be considered a violation of probation.

~~11.~~12. Violation of Probation

If a respondent owner has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent license, and probation shall be automatically extended until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent owner violates probation in any respect, the board, after giving respondent owner notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order ~~which~~ that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended~~,~~ until the petition to revoke probation or accusation is heard and decided.

~~If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty which was stayed.~~

~~12.~~13. Completion of Probation

Upon written notice by the board or its designee indicating successful completion of probation, respondent's license will be fully restored.

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OPTIONAL CONDITIONS OF PROBATION

~~1. Actual Suspension~~

~~As part of probation, respondent pharmacy is suspended from the operation of pharmacy for _____ days beginning the effective date of this decision.~~

~~During suspension, respondent pharmacy may not order, maintain or dispose of any dangerous drugs and devices or controlled substances. The pharmacy may not make demand or bill for any drugs or services during the period of suspension and may not process any claims for pharmacy services during the period of suspension, except as to services rendered prior to the effective date of the suspension period. The pharmacy shall not receive or transmit any prescription, new or refill, during the period of suspension. Where the pharmacy does not maintain dangerous drugs and devices or controlled substances in an area which can be closed off from the rest of the pharmacy and locked, the entire pharmacy must be closed during the period of suspension.~~

~~2.~~14. Community Services Program

Within sixty (60) days of the effective date of this decision, respondent owner shall submit to the board or its designee, for ~~its~~ prior approval, a community service program in which respondent shall provide free health-care related services ~~on a regular basis~~ to a community or charitable facility or agency for at least _____ hours per _____ for the first _____ of probation.

Within thirty (30) days of board approval thereof, respondent owner shall submit documentation to the board demonstrating commencement of the community service program. Respondent owner shall report on progress with the community service program in the quarterly reports.

Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.

~~3.~~15. Restitution (Appropriate in cases of drug diversion, theft, fraudulent billing, or patient harm resulting from negligence or incompetence.)

~~Within _____ days of the effective date of this decision, respondent owner shall pay restitution to _____ in the amount of $ _____. Failure to make restitution by this deadline shall be considered a violation of probation.~~

~~4.~~16. Separate File of Records

Respondent owner shall maintain and make available for inspection a separate file of all records pertaining to the acquisition or disposition of all controlled substances. Failure to maintain such file or make it available for inspection shall be considered a violation of probation.

~~5.~~17. Report of Controlled Substances

Respondent owner shall submit quarterly reports to the board detailing the total acquisition and

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disposition of such controlled substances as the board may direct. Respondent owner shall specify the manner of disposition (e.g., by prescription, due to burglary, etc.) or acquisition (e.g., from a manufacturer, from another retailer, etc.) of such controlled substances. Respondent owner shall report on a quarterly basis or as directed by the board. The report shall be delivered or mailed to the board no later than ten (10) days following the end of the reporting period. Failure to timely prepare or submit such reports shall be considered a violation of probation.

~~6.~~18. Surrender of DEA Permit

Within thirty (30) days of the effective date of this decision, ~~R~~respondent pharmacy shall surrender its federal Drug Enforcement Administration (DEA) permit to the DEA, for cancellation ~~within 30 days of the effective date of this decision~~. Respondent pharmacy shall provide documentary proof of such cancellation to the board or its designee. Thereafter, respondent pharmacy shall not apply/reapply for a DEA registration number without the prior written consent of the board or its designee.

Option: Respondent pharmacy may obtain a DEA permit restricted to Schedule(s) _____ controlled substance(s).

Option: Respondent pharmacy shall not order, receive, or retain any federal order forms, including 222 forms, for controlled substances.

~~7.~~19. Posted Notice of Suspension

Respondent owner shall prominently post a suspension notice provided by the board in a place conspicuous and readable to the public. The suspension notice shall remain posted during the entire period of ~~actual~~ suspension ordered by this decision.

Respondent owner shall not, directly or indirectly, engage in any conduct or make any statement, orally, electronically or in writing, which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the closure of the licensed entity.

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Attachment A-2

Proposed Language
Self-Assessment Form
And Written Comments Submitted

(Text follows next page.)

Subcommittee Recommendation to Pursue 15-day Notice
To Repeal Title 16 CCR §§ 1716.1 and 1716.2,
Adopt Title 16 CCR §§ 1735 – 1735.8 And
Amend Title 16 CCR §§ 1751 – 1751.8 Regarding Requirements for

Repeal Section 1716.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~**§1716.1. Compounding Unapproved Drugs for Prescriber Office Use.**~~

~~As used in Business and Professions Code Section 4052(a)(1), the following terms have the indicated meaning concerning the compounding of unapproved drugs for prescriber office use:~~

~~(a) "Reasonable quantity" means that quantity of an unapproved drug which:~~

~~(1) is sufficient for that prescriber's office use consistent with the expiration date of the product as set forth in section 1716.2(a)(3); and~~

~~(2) is reasonable considering the intended use of the compounded medication and nature of the prescriber's practice; and~~

~~(3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality and purity of the compounded medication.~~

~~(b) "Compounded medication" means medications actually compounded by the pharmacy supplying them to a prescriber.~~

~~(c) "Prescriber office use" means application or administration in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients as estimated by the prescriber.~~

~~Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4027, 4033, 4050, 4051, 4052, 4059, 4170 and 4171, Business and Professions Code.~~

Repeal Section 1716.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~**§1716.2. Record Requirements--Compounding for Future Furnishing.**~~

~~(a) For the purpose of compounding in quantities larger than required for immediate dispensing by a prescriber or for future dispensing upon prescription, a pharmacy shall maintain records that include, but are not limited to:~~

~~(1) The date of preparation.~~

~~(2) The lot numbers. These may be the manufacturer's lot numbers or new numbers assigned by the pharmacy. If the lot number is assigned by the pharmacy, the pharmacy must also record the original manufacturer's lot numbers and expiration dates, if known. If the original manufacturer's lot numbers and expiration dates are not known, the pharmacy shall record the source and acquisition date of the components.~~

~~(3) The expiration date of the finished product. This date must not exceed 180 days or the shortest expiration date of any component in the finished product unless a longer date is supported by stability studies in the same type of packaging as furnished to the prescriber. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.~~

~~(4) The signature or initials of the pharmacist performing the compounding.~~

~~(5) A formula for the compounded product. The formula must be maintained in a readily retrievable form.~~

~~(6) The name(s) of the manufacturer(s) of the raw materials.~~

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~~(7) The quantity in units of finished products or grams of raw materials.~~
~~(8) The package size and the number of units prepared.~~

~~Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4051, 4059, 4081 and 4332, Business and Professions Code.~~

Article 4.5 Compounding

Add Section 1735 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735. Compounding in Licensed Pharmacies

(a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

(1) Altering the dosage form or delivery system of a drug
(2) Altering the strength of a drug
(3) Combining components or active ingredients
(4) Preparing a drug product from chemicals or bulk drug substances

(b) "Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s) for oral, rectal topical, or injectable administration, nor does it include tablet splitting or the addition of flavoring agent(s) to enhance palatability.

(c) "Compounding" does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace.

(d) The parameters and requirements stated by this Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile injectable compounding are stated by Article 7 (Section 1751 et seq.).

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Add Section 1735.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.1. Compounding Definitions

(a) "Integrity" means retention of potency until the expiration date noted on the label.

(b) "Potency" means active ingredient strength within +/- 10% of the labeled amount.

(c) "Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and absence of active ingredients other than those noted on the label.

(d) "Strength" means amount of active ingredient per unit of a compounded drug product.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Add Section 1735.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.2. Compounding Limitations and Requirements

(a) Except as specified in (b) and (c), no drug product shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug product either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

(b) A pharmacy may prepare and store a limited quantity of a compounded drug product in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.

(c) Pursuant to Business and Professions Code section 4052(a)(1), a "reasonable quantity" of compounded drug product may be furnished to a prescriber for office use upon prescriber order, where "reasonable quantity" is that amount of compounded drug product that:

(1) is sufficient for administration or application to patients in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients, as estimated by the prescriber; and
(2) is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and
(3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product.

(d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:

(1) Active ingredients to be used.
(2) Inactive ingredients to be used.
(3) Process and/or procedure used to prepare the drug.
(4) Quality reviews required at each step in preparation of the drug.
(5) Post-compounding process or procedures required, if any.
(6) Expiration dating requirements.

(e) Where a pharmacy does not routinely compound a particular drug product, the master formula record for that product may be recorded on the prescription document itself.

(f) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.

(g) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendial and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.

(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

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(i) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product.

(j) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment form for compounding pharmacies developed by the board (form 17m-39 rev. 10/07). That form contains a fist section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of odd-numbered each year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Add Section 1735.3 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.3. Records of Compounded Drug Products

(a) For each compounded drug product, the pharmacy records shall include:

(1) The master formula record.
(2) The date the drug product was compounded.
(3) The identity of the pharmacy personnel who compounded the drug product.
(4) The identity of the pharmacist reviewing the final drug product.
(5) The quantity of each component used in compounding the drug product.
(6) The manufacturer and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.
(7) The equipment used in compounding the drug product.
(8) A pharmacy assigned reference or lot number for the compounded drug product.
(9) The expiration date of the final compounded drug product.
(10) The quantity or amount of drug product compounded.

(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.

(c) Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the Food and Drug Administration.

(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Add Section 1735.4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.4. Labeling of Compounded Drug Products

(a) In addition to the labeling information required under Business and Professions Code section 4076, the label of a compounded drug product shall contain the generic name(s) of the principal active ingredient(s).

(b) A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.

(c) Drug products compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a) and (b) shall be labeled with at least the name(s) of the active ingredient(s), concentration or strength, volume or weight, pharmacy reference or lot number, and expiration date.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

Add Section 1735.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.5. Compounding Policies and Procedures

(a) Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.

(b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.

(c) The policy and procedure manual shall include the following

(1) Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual.
(2) Documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product.
(3) The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.
(4) Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.
(5) Documentation of the methodology used to determine appropriate expiration dates for compounded drug products.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Add Section 1735.6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.6. Compounding Facilities and Equipment

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(a) Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products. Where applicable, this shall include records of certification(s) of facilities or equipment.

(b) Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications.

(c) Any equipment used to compound drug products for which calibration or adjustment is appropriate shall be calibrated prior to use to ensure accuracy. Documentation of each such calibration shall be recorded in writing and these records of calibration shall be maintained and retained in the pharmacy.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Add Section 1735.7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.7. Training of Compounding Staff

(a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.

(b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.

(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug product.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Deletions to the regulatory text are indicated by double strike-through, thus: ~~deleted language~~. Additions to the regulatory text are indicated by a double underline, thus: added language.

Add Section 1735.8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.8. Compounding Quality Assurance

(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.

(b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.

(c) The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula.

(d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality, or labeled strength.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Deletions to the regulatory text are indicated by double strike-through, thus: ~~deleted language~~. Additions to the regulatory text are indicated by a double underline, thus: added language.

Article 7 Sterile Injectable Compounding

Amend Section 1751 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751. Sterile Injectable Compounding; Compounding Area.

(a) Any pharmacy engaged in compounding sterile injectable drug products shall conform to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile injectable compounding.

(b) ~~The~~ Any pharmacy doing sterile injectable compounding shall have a designated area for the preparation of sterile injectable products which shall meet the following standards:

(1) Clean Room and Work Station Requirements, shall be in accordance with Section 490A.3.1 of Title 24, Part 2, Chapter 4A of the California Code of Regulations.
(2) Walls, ceilings and floors shall be constructed in accordance with Section 490A.3 of Title 24, Part 2, Chapter 4A of the California Code of Regulations.
(3) Be ventilated in a manner in accordance with Section 505.12 of Title 24, Part 4, Chapter 5 of the California Code of Regulations.
(4) Be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the United States General Services Administration. Certification records must be retained for at least 3 years.
(5) The pharmacy shall be arranged in accordance with Section 490A.3 of Title 24, Part 2, Chapter 4A of the California Code of Regulations. Items related to the compounding of sterile injectable products within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.
(6) A sink shall be included in accordance ~~in~~ with Section 490A.3.4 of Title 24, Part 2, Chapter 4A of the California Code of Regulations.
(7) There shall be a refrigerator and/or freezer of sufficient capacity to meet the storage requirements for all material requiring refrigeration.

(c) Any pharmacy compounding a sterile injectable product from one or more non-sterile ingredients shall comply with Business and Professions Code section 4127.7.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4127 and 4127.7, Business and Professions Code; and Section 18944(a), Health and Safety Code.

Deletions to the regulatory text are indicated by double strike-through, thus: ~~deleted language~~. Additions to the regulatory text are indicated by a double underline, thus: added language.

Renumber section 1751.3 to new section 1751.1 and amend section 1751.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~§1751.3.~~ 1751.1. Sterile Injectable Recordkeeping Requirements.

(a) Pharmacies compounding sterile injectable products for future use pursuant to section ~~1716.1~~ 1735.2 shall, in addition to those records required by section ~~1716.2~~ 1735.3, ~~have~~ make and keep records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.

(b) In addition to the records required by section 1735.3 and subdivisions (a), for sterile products compounded from one or more non-sterile ingredients, the following records must be ~~maintained for at least three years~~ made and kept by the pharmacy:

(1) The training and competency evaluation of employees in sterile product procedures.
(2) Refrigerator and freezer temperatures.
(3) Certification of the sterile compounding environment.
(4) Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).
(5) Inspection for expired or recalled pharmaceutical products or raw ingredients.
(6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.

(c) ~~Pharmacies shall maintain records of validation processes as required by Section 1751.7 (b) for three years~~ Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Amend Section 1751.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.2. Sterile Injectable Labeling Requirements.

In addition ~~to existing labeling requirements~~ to the labeling information required under Business and Professions Code section 4076 and section 1735.4, a pharmacy which compounds sterile injectable products shall include the following information on the labels for those products:

(a) Telephone number of the pharmacy, except for sterile injectable products dispensed for inpatients of a hospital pharmacy.

(b) Name and concentrations of ingredients contained in the sterile injectable product.

(c) Instructions for storage and handling.

(d) All cytotoxic agents shall bear a special label which states "Chemotherapy -Dispose of Properly."

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

Deletions to the regulatory text are indicated by double strike-through, thus: ~~deleted language~~. Additions to the regulatory text are indicated by a double underline, thus: added language.

Renumber section 1751.02 to new section 1751.3 and amend section 1751.3 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§~~1751.02.~~ 1751.3. Sterile Injectable Policies and Procedures.

(a) ~~Written policies and procedures associated with the pharmacy's preparation and dispensing of sterile injectable products shall include, but not be limited to~~ Any pharmacy engaged in compounding sterile injectable drug products shall maintain a written policy and procedure manual for compounding that includes, in addition to the elements required by section 1735.5, written policies and procedures regarding the following:

(1) Compounding, filling, and labeling of sterile injectable compounds.
(2) Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration.
(3) Equipment and supplies.
(4) Training of staff in the preparation of sterile injectable products.
(5) Procedures for handling cytotoxic agents.
(6) Quality assurance program.
(7) Record keeping requirements.

(b) The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist.

(c) Pharmacies compounding sterile injectable products shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic residues. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

(d) Pharmacies compounding sterile injectable products from one or more non-sterile ingredients must have written policies and procedures that comply with the following:

(1) All written policies and procedures shall be immediately available to all personnel involved in these activities and board inspectors.
(2) All personnel involved must read the policies and procedures before compounding sterile injectable products, and any additions, revisions, and deletions to the written policies and procedures must be communicated to all personnel involved in sterile compounding.
(3) Policies and procedures must address at least the following:
    (A) Competency evaluation.
    (B) Storage and handling of products and supplies.
    (C) Storage and delivery of final products.
    (D) Process validation.
    (E) Personnel access and movement of materials into and near the controlled area.
    (F) Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations).
    (G) Regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules and the alternation of disinfectants in lieu of complying with this subdivision.
    (H) Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area.

Deletions to the regulatory text are indicated by double strike-through, thus: ~~deleted language~~. Additions to the regulatory text are indicated by a double underline, thus: added language.

(I) For sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets and for appropriate documentation.
(J) Sterilization.
(K) End-product evaluation and testing.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Renumber section 1751.01 to new section 1751.4 and amend section 1751.4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~§1751.01.~~ 1751.4. Facility and Equipment Standards for Sterile Injectable Compounding ~~from Non-Sterile Ingredients.~~

(a) No sterile injectable product shall be ~~prepared~~ compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile injectable drug products.

(b) During the preparation of sterile injectable products, access to the designated area or cleanroom must be limited to those individuals who are properly attired.

(c) All equipment used in the designated area or cleanroom must be made of a material that can be easily cleaned and disinfected.

(d) Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination.

(e) Pharmacies preparing parenteral cytotoxic agents shall ~~be~~ do so in accordance with Section 4-1106(b) of Title 24 of the California Administrative Code, requiring a laminar air flow hood. The hood must be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications. Certification records must be retained for at least 3 years.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code; and Section 18944(a), Health and Safety Code.

Repeal Section 1751.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~§1751.1. Laminar Flow Biological Safety Cabinet.~~

~~Pharmacies preparing parenteral cytotoxic agents shall be in accordance with Section 4-1106(b) of Title 24 of the California Administrative Code. The hood must be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May,~~

~~1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications. Certification records must be retained for at least 3 years.~~

~~Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code; and Section 18944(a), Health and Safety Code.~~

Repeal Section 1751.3 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~§1751.3. Recordkeeping Requirements.~~

~~(a) Pharmacies compounding sterile injectable products for future use pursuant to section 1716.1 1735.2 shall, in addition to those records required by section 1716.2 1735.3, have records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.~~

~~(b) In addition to the records required by subdivisions (a), for sterile products compounded from one or more non-sterile ingredients the following records must be maintained for at least three years:~~

~~(1) The training and competency evaluation of employees in sterile product procedures.~~
~~(2) Refrigerator and freezer temperatures.~~
~~(3) Certification of the sterile compounding environment.~~
~~(4) Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).~~
~~(5) Inspection for expired or recalled pharmaceutical products or raw ingredients.~~
~~(6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.~~

~~(c) Pharmacies shall maintain records of validation processes as required by Section 1751.7 (b) for three years.~~

~~Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code~~

Renumber section 1751.4 to new section 1751.5 and amend section 1751.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~§1751.4.~~ 1751.5. Sterile Injectable Compounding Attire.

(a) When preparing cytotoxic agents, gowns and gloves shall be worn.

(b) When compounding sterile products from one or more non-sterile ingredients the following standards must be met:

(1) Cleanroom garb consisting of a low-shedding coverall, head cover, face mask, and shoe covers must be worn inside the designated area at all times.
(2) Cleanroom garb must be donned and removed outside the designated area.
(3) Hand, finger, and wrist jewelry must be eliminated. If jewelry cannot be removed then it must be thoroughly cleaned and covered with a sterile glove.
(4) Head and facial hair must be kept out of the critical area or be covered.
(5) Gloves made of low-shedding materials are required.

(c) The requirements of ~~this~~ subdivision (b) do not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Renumber section 1751.5 to new section 1751.6 and amend section 1751.6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~§1751.5.~~ 1751.6. Training of Sterile Injectable Compounding Staff, Patient, and Caregiver.

(a) Consultation shall be available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy.

(b) The pharmacist-in-charge shall be responsible to ensure all pharmacy personnel engaging in compounding sterile injectable drug products shall have training and demonstrated competence in the safe handling and compounding of sterile injectable products, including cytotoxic agents if the pharmacy compounds products with cytotoxic agents.

(c) Records of training and demonstrated competence shall be available for each individual and shall be retained for three years beyond the period of employment.

(d) The pharmacist-in-charge shall be responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile injectable products.

(e) Pharmacies that compound sterile products from one or more non-sterile ingredients must comply with the following training requirements:

(1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:
   (A) Aseptic technique.
   (B) Pharmaceutical calculations and terminology.
   (C) Sterile product compounding documentation.
   (D) Quality assurance procedures.
   (E) Aseptic preparation procedures.
   (F) Proper gowning and gloving technique.
   (G) General conduct in the controlled area.
   (H) Cleaning, sanitizing, and maintaining equipment used in the controlled area.
   (I) Sterilization techniques.
   (J) Container, equipment, and closure system selection.

(2) Each person assigned to the controlled area must successfully complete practical skills training in aseptic technique and aseptic area practices. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's proficiency and continuing training needs must be reassessed every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Repeal Section 1751.6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~**§1751.6. Disposal of Waste Material.**~~

~~Pharmacies compounding sterile injectable products shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic residues. The procedures shall include cleanup of spills and shall be in conformance with local health jurisdiction.~~

~~Authority cited: Section 4005 Business and Professions Code. Reference: Section 4005 Business and Professions Code.~~

Amend 1751.7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.7. Sterile Injectable Compounding Quality Assurance and Process Validation.

(a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, ~~There shall be~~ a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following:

(1) Cleaning and sanitization of the parenteral medication preparation area.
(2) The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.
(3) Actions to be taken in the event of a drug recall.
(4) Written justification of the chosen expiration dates for compounded sterile injectable products.

(b) Each individual involved in the preparation of sterile injectable products must first successfully complete a validation process on technique before being allowed to prepare sterile injectable products. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The same personnel, procedures, equipment, and materials ~~are~~ must be involved. Completed medium samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated. Personnel competency must be revalidated at least every twelve months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. Revalidation must be documented.

(c) Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.

(d) Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Renumber section 1751.9 to new section 1751.8 and amend section 1751.8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~§1751.9.~~ 1751.8. Sterile Injectable Compounding Reference Materials.

In any pharmacy engaged in compounding sterile injectable drug products, ~~T~~there shall be current and appropriate reference materials regarding the compounding of sterile injectable products located in or immediately available to the pharmacy.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Deletions to the regulatory text are indicated by double strike-through, thus: ~~deleted language~~. Additions to the regulatory text are indicated by a double underline, thus: added language.

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENNEGGER, GOVERNOR

COMMUNITY PHARMACY & HOSPITAL OUTPATIENT PHARMACY COMPOUNDING SELF-ASSESSMENT

The California Code of Regulations section 1735.2 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code that compounds drug product to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **The assessment shall be performed before July 1 of every odd-numbered year. The pharmacist-in-charge must also complete a self-assessment within 30 days whenever; (1) a new pharmacy permit has been issued, or (2) there is a change in the pharmacist-in-charge. The primary purpose of the self-assessment is to promote compliance through self-examination and education.**

The self-assessment must be competed in entirety and may be completed online, printed and retained in the pharmacy. Do not copy a previous assessment.

Note: If a hospital pharmacy dispenses prescriptions for outpatient use, a Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment must be completed in addition to the Hospital Pharmacy Self-Assessment.

Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

Pharmacy Name: _____

Address: _____ Phone: _____

Ownership: Sole Owner ☐ Partnership ☐ Corporation ☐ LLC ☐
Non-Licensed Owner ☐ Other (please specify) ☐ _____

Permit #: _____ Exp. Date:_____ Other Permit #: _____ Exp. Date: _____

Licensed Sterile Compounding Permit # _____ or Accredited by: _____

DEA Registration #: _____ Exp. Date: _____ Date of DEA Inventory: _____

Hours: *Daily*_____ *Sat*_____ *Sun.* _____ *24 Hours* _____

PIC: _____ RPH # _____ Exp. Date: _____

Pharmacy Staff (pharmacists, intern pharmacists, pharmacy technicians assigned to compounding duties):
(Please use an additional sheet if necessary)

2. _____ RPH # _____ Exp. Date: _____

3. _____ RPH # _____ Exp. Date: _____

4. _____ RPH # _____ Exp. Date: _____

5. _____ RPH # _____ Exp. Date: _____

6. _____ RPH # _____ Exp. Date: _____

7. _____ INT # _____ Exp. Date: _____

8. _____ INT # _____ Exp. Date: _____

9. _____ INT # _____ Exp. Date: _____

10. _____ TCH # _____ Exp. Date: _____

11. _____ TCH # _____ Exp. Date: _____

12. _____ TCH # _____ Exp. Date: _____

13. _____ TCH # _____ Exp. Date: _____

14. _____ TCH # _____ Exp. Date: _____

15. _____ TCH # _____ Exp. Date: _____

16. _____ TCH # _____ Exp. Date: _____

COMMUNITY PHARMACY & HOSPITAL OUTPATIENT PHARMACY COMPOUNDING SELF-ASSESSMENT

All references to the California Code of Regulations (CCR) are to Title 16 unless otherwise noted.

Please mark the appropriate box for each question. If "NO", enter an explanation on "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, you may add additional sheets.

COMPOUNDING

1. Definitions (CCR 1735 and 1735.1)

Yes No N/A

☐☐☐ The pharmacy compounds prescriptions as defined in CCR 1735.

☐☐☐ The compounding pharmacist understands the definitions of integrity, potency, quality and strength as defined in CCR 1735.1.

2. Compounded Limitations and Requirements (CCR 1735.2)

The pharmacy does not compound drug product prior to receipt of a valid prescription unless under the following conditions. (CCR 1735.2[a])

Yes No N/A

☐☐☐ The pharmacy prepares and stores a limited quantity of a compounded drug product in advance of receipt of a patient specific prescription solely in such quantity as is necessary to ensure continuity of care of an identified patient population as defined. (CCR 1735.2[b])

☐☐☐ The pharmacy compounds a reasonable quantity of drug product that is furnished to a prescriber for office use upon prescriber order as allowed in CCR 1735.2 (c) that:

Is sufficient for administration or application to patients in the prescriber's office or for distribution of not more than a 72-hour supply, (CCR 1735.2[c][1])

Is reasonable considering the intended use of the complounded medication and the nature of the prescriber's practice, (CCR 1735.2[c][2]) AND

Is an amount, which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength for any individual prescriber or for all prescribers taken as a whole. (CCR 1735.2[c][3])

☐☐☐ The pharmacy does not compound medication until it has prepared a written master formula that includes the following elements (CCR 1735.2[d][1-6]):

Active ingredients used.

Inactive ingredients used.

Process and/or procedure used to prepare the drug.

Quality reviews required at each step in the preparation of the drug.

Post-compounding process or procedures if required.

Expiration dating requirements.

☐☐☐ The master formula for a drug product that is not routinely compounded by the pharmacy is recorded on the prescription document itself. (CCR 1735.2 [e])

☐☐☐ All chemicals, bulk drug substances, drug products and other components for compounding are stored and used according to compendial and other applicable requirements to maintain their integrity, potency, quality and labeled strength. (CCR 1735.2 [g])

☐☐☐ Compounded drug products are given an expiration date representing the date beyond which, in the professional judgment of the pharmacist, it should not be used as defined in CCR 1735.2 (h) and does not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product. (CCR 1735.2[h])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

3. Records of Compounded Drug Products (CCR 1735.3)

Yes No N/A

☐☐☐ A record for each compounded drug product includes the following (CCR 1735.3[a][1-10]):

The master formula record.

The date the drug product was compounded.

The identity of the pharmacy personnel who compounded the drug product.

The identity of the pharmacist reviewing the final drug product.

The quantity of each component used in compounding the drug product.

The manufacturer or supplier and lot number of each component.

The equipment used in compounding the drug product.

The pharmacy assigned reference or lot number for the compounded drug product.

The expiration date of the final compounded drug product.

The quantity or amount of drug product compounded.

☐☐☐ The pharmacy maintains records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products and components used in compounding. (CCR 1735.3 [b])

☐☐☐ Chemicals, bulk drug substances, drug products, and components used to compound drug products are obtained from reliable suppliers. (CCR 1735.3 [c])

☐☐☐ The pharmacy acquires and retains any available certificates of purity or analysis for chemicals, bulk drug substances, drug products and components used in compounding. (This is not a requirement for drug products approved by the FDA.) (CCR 1735.3 [c])

☐☐☐ The pharmacy maintains and retains all records required in the pharmacy in a readily retrievable form for at least three years (CCR 1735.3 [d]).

4. Labeling of Compounded Drug Products (CCR 1735.4)

Yes No N/A

☐☐☐ The label of the compounded drug product contains the generic name(s) of the principle active ingredient(s). (CCR 1735.4[a])

☐☐☐ The prescription label contains all the information required in B&PC 4076. (CCR 1735.4[a]

☐☐☐ The container or receipt contains a statement that the drug has been compounded by the pharmacy. (CCR 1735.4[b])

☐☐☐ Drug products compounded into unit-dose containers that are too small or otherwise impractical for full compliance are labeled with the name(s) of the active ingredient(s), concentration of strength, volume or weight, and expiration date. (CCR 1735.4[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

5. Compounding Policies and Procedures (CCR 1735.5)

Yes No N/A

☐☐☐ The pharmacy maintains a written policy and procedure manual for compounding that establishes the following (CCR 1735.5 [a]):

Procurement procedures.

Methodologies for the formulation and compounding of drugs.

Facilities and equipment cleaning, maintenance and operations.

Other standard operating procedures related to compounding.

☐☐☐ The policy and procedure manual is reviewed on an annual basis by the pharmacist-in-charge and is updated whenever changes in process are implemented. (CCR 1735.5 [b])

☐☐☐ The policy and procedure manual includes procedures for notifying staff assigned to compounding duties of any changes in process or to the policy and procedure manual. (CCR 1735.5[c])

☐☐☐ The manual includes documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product. (CCR 1735.5[d])

☐☐☐ The manual includes procedures for maintaining, storing, calibrating, cleaning and disinfecting equipment used in compounding and for training on these procedures. (CCR 1735.5[e])

☐☐☐ The manual includes documentation on the methodology used to test integrity, potency, quality and labeled strength of compounded drug products. (CCR 1735.5[f])

☐☐☐ The manual includes documentation of the methodology used to determine appropriate expiration dates for compounded drug products. (CCR 1735.5[g])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

6. Compounding Facilities and Equipment (CCR 1735.6)

Yes No N/A

☐☐☐ The pharmacy maintains written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products to include records of certification of facilities or equipment, if applicable. (CCR 1735.6[a])

☐☐☐ All equipment used to compound drug products is stored, used and maintained in accordance with manufacturers' specifications. (CCR 1735.6[b])

☐☐☐ All equipment used to compound drug products is calibrated prior to used to ensure accuracy. (CCR 1735.6[c])

☐☐☐ Documentation of each calibration is recorded in writing and maintained and retained in the pharmacy. (CCR 1735.6[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

7. Training of Compounding Staff (CCR 1735.7)

Yes No N/A

☐☐☐ The pharmacy maintains written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform assigned responsibilities relating to compounding. (CCR 1735.7[a])

☐☐☐ The pharmacy develops and maintains an on-going competency evaluation process for pharmacy personnel involved in compounding. (CCR 1735.7[b])

☐☐☐ Documentation on any and all such training for pharmacy personnel is maintained. (CCR 1735.7[b])

☐☐☐ Pharmacy personnel assigned to compounding duties demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug product. (CCR 1735.7[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

8. Compounding Quality Assurance (CCR 1735.8)

Yes No N/A

☐☐☐ The pharmacy maintains as part of its written policies and procedures, a written quality assurance plan to monitor and ensure the integrity, potency, quality and labeled strength of compounded drug products. (CCR 1735.8[a])

☐☐☐ The pharmacy's quality assurance plan includes the written procedures and standards for the following:

Verification, monitoring and review of the adequacy of the compounding processes as well as documentation of review of those processes by qualified pharmacy personnel. (CCR 1735.8[b])

Qualitative and quantitative integrity, potency, quality and labeled strength analysis of compounded drug products. (CCR 175.8[c])

Such reports are retained by the pharmacy and collated with the compounding record and master formula. (CCR 1735.8[c])

Scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality or labeled strength. (CCR 1735.8[d])

COMPOUNDING STERILE INJECTABLE DRUGS

FOR PHARMACIES THAT COMPOUND STERILE INJECTABLE DRUGS

Yes No N/A

☐☐☐ Pharmacy has a board issued Licensed Sterile Compounding permit or has current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other board approved accreditation agency. (B&PC 4127.1[a] and 4127.1[d])

LSC # _____ OR

Name of accreditation agency _____

9. Compounding Drug for Other Pharmacy for Parenteral Therapy (B&PC 4123)

Yes No N/A

☐☐☐ The pharmacy contracts to compound a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy.

The contractual arrangement is reported to the board within 30 days of commencing that compounding.

10. Sterile Injectable Compounding; Compounding Area (CCR 1751)

Yes No N/A

☐☐☐ If the pharmacy compounds sterile injectable drugs from a nonsterile source, the pharmacy has a designated area or cleanroom for the preparation of sterile products that has one the following:

An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. A positive air pressure differential in the cleanroom that is relative to adjacent areas; (B&PC 4127.7[a])

An ISO class 5 cleanroom (B&PC 4127.7[b])

A barrier isolator that provides an ISO class 5 environment for compounding. (B&PC 4127.7[c])

☐☐☐ The cleanroom walls, ceiling and floors are made of non-porous, cleanable surfaces and the room is well ventilated (CCR 1751)

The laminar airflow hoods and clean room are certified annually; (CCR 1751)

Supplies are stored in a manner, which maintains integrity of an aseptic environment; (CCR 1751)

A sink with hot and cold running water; (CCR 1751)

A refrigerator of sufficient capacity to meet the storage requirements for all material requiring refrigeration. (CCR 1751)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

11. Sterile Injectable Recordkeeping Requirements. (CCR 1751.1)

Yes No N/A

☐☐☐ Pharmacy records are made and kept for sterile injectable products produced for future use (pursuant to section 1735.2), in addition to record requirements of section 1735.3, contain the name, lot number, amount, and date on which the products were provided to a prescriber. (CCR 1751.1[a])

☐☐☐ Records for sterile products compounded from one or more non-sterile ingredients are made and kept and contain the following: (CCR 1751.1[b][1-6])

The training and competency evaluation of employees in sterile product procedures;

Refrigerator and freezer temperatures;

Certification of the sterile compounding environment;

Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment);

Inspection for expired or recalled pharmaceutical products or raw ingredients; and

Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.

☐☐☐ The pharmacy maintains and retains all records required in the pharmacy in a readily retrievable form for at least three years from the date the record was created. (CCR 1751.1[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

12. Sterile Injectable Labeling Requirements (CCR 1751.2)

Yes No N/A

☐☐☐ The pharmacy's compounded sterile injectable product labels contain: (CCR 1751.2[a-d])

Telephone number of the pharmacy, unless dispensed for a hospital in-patient;

Name and concentrations of ingredients contained in the product;

Instructions for storage and handling; and

A special label that states "Chemotherapy—Dispose of Properly" for all cytotoxic agents.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

13. Sterile Injectable Policies and Procedures (CCR 1751.3)

Yes No N/A

☐☐☐ The pharmacy has a written manual documenting the policies and procedures associated with the preparation and dispensing of sterile injectable products and includes: (CCR 1751.2[a][1-7])

Compounding, filling, and labeling of sterile injectable compounds;

Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration;

Equipment and supplies;

Training of staff in preparation of sterile injectable products;

Training of patient and/or caregiver in the administration of compounded sterile injectable products;

Procedures for the handling and disposal of cytotoxic agents;

Quality assurance program; and

Record keeping requirements.

☐☐☐ Ingredients and compounding process for each preparation is determined in writing and reviewed by a pharmacist before compounding begins. (CCR 1751.3[b])

☐☐☐ Policies and procedures address the disposal of infectious materials and/or materials containing cytotoxic residues and include cleanup of spills in conformance with local health jurisdictions. (CCR 1751.3 [c])

☐☐☐ If compounding sterile injectable products from one or more non-sterile ingredients, the pharmacy has written policies and procedures that comply with the following: (CCR 1751.3[d][1-3])

Policies and procedures are immediately available to all compounding personnel and board inspectors (CCR 1751.3[d][1]); and

All compounding personnel have read the policies and procedures, any additions, revisions, and deletions before compounding. (CCR 1751.3 [d][2])

☐☐☐ Policies and procedures address the following: (CCR 1751.3 [d][3] [A-K])

Competency evaluation;

Storage and handling of products and supplies;

Storage and delivery of final products;

Process validation;

Personnel access and movement of materials into and near the controlled area;

Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations;

A regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules;

Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area;

For sterile batch compounding, written policies and procedures for the use of master formulas and work sheets and for appropriate documentation;

Sterilization; and

End-product evaluation and testing.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

14. Facility & Equipment Standards for Sterile Injectable Compounding (CCR 1751.4)

Yes No N/A

☐☐☐ The compounding environment meets criteria specified in the pharmacy's written policies and procedures for safe compounding of sterile injectable drugs. (CCR 1751.4[a])

☐☐☐ Only those who are properly attired pursuant to (CCR 1751.5) are allowed in the cleanroom during the preparation of sterile injectable products. (CCR 1751.4[b])

☐☐☐ All equipment used in the designated area or cleanroom is made of easily cleaned and disinfected material. (CCR 1751.4[c])

☐☐☐ Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools are disinfected weekly and after any unanticipated event that could increase risk of contamination (CCR 1751.4[d])

☐☐☐ The preparation of parenteral cyctotoxic agents is done in accordance with Section 4-1006(b) of Title 24 of the California Administrative Code and includes: (CCR 1751.4[e])

A laminar airflow hood, which is certified annually.

Certification records are maintained for at least three years.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

15. Sterile Injectable Compounding Attire (CCR 1751.5)

Yes No N/A

☐☐☐ When preparing cytotoxic agents, gowns and gloves are worn.(CCR 1751.5[a])

☐☐☐ When compounding sterile products from one or more non-sterile ingredients and a barrier isolator is not used: (CCR 1751.5[b][1-5])

Cleanroom garb is donned and removed outside the designated area; (CCR 1751.5[b][2])

Individuals in the cleanroom wear a low-shedding coverall, head cover, face mask, and shoe covers; (CCR 1751.5[b][1])

No hand, finger, or wrist jewelry is worn or if the jewelry cannot be removed, it is cleaned and covered with a sterile glove; (CCR 1751.5[b][3])

Head and facial hair is kept out of critical area or covered (CCR 1751.5[b][4]); and

Gloves of low-shedding material are worn. (CCR 1751.5[b][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

16. Training of Sterile Injectable Compouding Staff, Patient, and Caregiver (CCR 1751.6)

Yes	No	N/A	
☐	☐	☐	Consultation is available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy. (CCR 1751.6[a])
☐	☐	☐	The pharmacist-in-charge ensures that all pharmacy personnel engaging in compounding sterile injectable drug products has training and demonstrated competence in the safe handling of those products, including cytotoxic agents if the pharmacy compounds such agents. (CCR 1751.6[b])
☐	☐	☐	Records of training and demonstrated competence are available for each individual and are retained for three years beyond the employment period. (CCR 1751.6[c])
☐	☐	☐	The pharmacist-in-charge ensures the continuing competence of pharmacy personnel engaged in compounding sterile injectable products. (CCR 1751.6[d])
☐	☐	☐	When compounding sterile products from one or more non-sterile ingredients, the pharmacy complies with the following training requirements: (CCR 1751.6[e])
☐	☐	☐	The pharmacy follows a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation addresses the following: (CCR 1751.6[e][1][A-J])

Aseptic technique;

Pharmaceutical calculations and terminology;

Sterile product compounding documentation;

Quality assurance procedures;

Proper gowning and gloving technique;

General conduct in the controlled area;

Cleaning, sanitizing, and maintaining equipment used in the controlled area;

Sterilization techniques; and

Container, equipment, and closure system selection.

☐☐☐ Each person assigned to the controlled area successfully completes practical skills training in aseptic technique and aseptic area practices. (CCR 1751.6[e][2])

Evaluation includes written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. (CCR 1751.6[e][2])

Each person's proficiency and continuing training is reassessed every 12 months. (CCR 1751.6[e][2])

Results of these assessments are documented and retained in the pharmacy for three years. (CCR 1751.6[e][2])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

17. Sterile Injectable Compounding Quality Assurance and Process Validation (CCR 1751.7)

Yes No N/A

☐☐☐ There is a written, documented, ongoing quality assurance program maintained by the pharmacy that monitors personnel performance, equipment, and facilities, and the pharmacist-in-charge assures that the end-product meets the required specifications by periodic sampling. (CCR 1751.7[a])

☐☐☐ The Quality Assurance Program contains at least the following: (CCR 1751.7[a][1-4])

Cleaning and sanitization of the parenteral medication preparation area;

The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature;

Actions to be taken in the event of a drug recall; and

Written justification of the chosen expiration dates for compounded sterile injectable products in accordance with CCR 1735.2[h]).

☐☐☐ Each individual involved in the preparation of sterile injectable products successfully completes a validation process on technique before being allowed to prepare sterile injectable products. (CCR 1751.7[b])

The validation process is carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. (CCR 1751.7[b])

The validation process is representative of all types of manipulations, products and batch sizes the individual is expected to prepare. (CCR 1751.7[b])

The same personnel, procedures, equipment, and materials are involved. (CCR 1751.7[b])

Completed medium samples are incubated. (CCR 1751.7[b])

If microbial growth is detected, the sterile preparation process is evaluated, corrective action taken, and the validation process is repeated. (CCR 1751.7[b])

Personnel competency is revalidated and documented at least every 12 months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever aseptic techniques are observed. (CCR 1751.7[b])

☐☐☐ Batch produced sterile injectable drug products compounded from one or more non-sterile ingredients are subject to documented end product testing for sterility and pyrogens and are quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. (CCR 1751.7[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

18. Sterile Injectable Compounding Reference Materials (CCR 1751.8)

Yes No N/A

☐☐☐ Current and appropriate reference materials regarding the compounding of sterile injectable products are maintained or immediately available to the pharmacy. (CCR 1751.8)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (Please print) _____, RPH # _____ hereby certify that I have completed the self-assessment of this pharmacy of which I am the pharmacist-in-charge. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury that the information contained in this self-assessment form is true and correct.

Signature _____ Date _____
(Pharmacist-in-Charge)

Stephan Flascha
<flascha@ca.rr.com>

09/04/2008 06:25 AM

To karen_cates@dca.ca.gov

cc

bcc

Subject 30 year veteran hospital pharmacist concerned about documentation requirements.

Dear Ms. Karen Cates:

As a hospital pharmacist licensed since 1978, 30 years, I am really concerned about the documentation requirements in Compounding in an IV room in a major hospital. We are required to prepare there are proabally a thousand items involved in one shift which are activated.

Just consider a t supermarket check out counter you want the cash register noted Manufacturer, Expiration Date and Lot number of every item you buy. We do that if we compound bigger bactaches like a manufacturer but most items are for a personalized use.

Please consider this requirement as undoable. It will make the environment so "crazy-Busy" that you will have more centennial events.

Sincerly

Dr. Stephan Flascha R.Ph. Pharm.D.
Kaiser Sunset

"Baertsch, Suzanne"
<BaertsS@sutterhealth.org>

09/04/2008 12:15 PM

To <Karen_cates@dca.ca.gov>
cc <philip@cshp.org>
bcc
Subject Board of Pharmacy new compounding regulations

I just heard about the proposed compounding regulations, and while I understand the concern for patient safety, I think these regulations will have the opposit effect.

I work in a hospital where we compound hundreds of IVs daily in a sterile environment. The additional time it would take for all this record keeping would mean we would have to cut back in other area. We are already stretched too thin, and this will make it worse for overall patient care, with little benefit.

I am especially concerned about 1st dose antibiotics or cardiovasular drips. This may result in a further delay to patient therapy.

I understand it is valuable to be able to trace back how something is made, but remember, this still does not PREVENT an errror. It only allows you to see what the error is.

In summary, I strongly feel these new regulations will be a detriment to patient care and our healthcare system as a whole, especially in regard to IV medications.

Suzanne Baertsch
NICU Pharmacist
Alta Bates Summit Medical Center
Berkeley, CA 94705

"Hass, Deborah"
<DHass@stanfordmed.org>
09/05/2008 12:54 PM

To karen_cates@dca.ca.gov
cc philip@cshp.org
bcc
Subject New Board of Pharmacy Regulations regarding IV Compounding

Dear Ms. Cates: I am a clincial pharmacist at Stanford University Hospital in Stanford, CA. I am writing to strongly object to the newly proposed regulations regarding compounding sterile IV products:

I would agree with the CSHP (and am quoting them) in asking for an exemption of logging and pharmacy lot number assignment/labeling for those "immediate use" products as defined by USP. These products are needed urgently and there is a potential of delay with the additional record keeping requirements with no benefit to the patient. Any future recall of product would be moot as the IV would be already administered as an immediate-use. This means every STAT alteplase, epinephrine, diltiazem or other life-saving medication prepared by a pharmacist during cardiac resuscitation, in the emergency department, in the operating rooms or in other critical care areas would be delayed a few minutes longer to assure logging, assignment, and labeling of the IV bag with a pharmacy lot number.

In addition, for all products, whether STAT or non-urgent, extensive recordkeeping would be required for each product prepared and maintained for a minimum of 3 years. Considering the thousands of records daily that would be generated here at Stanford to meet the requirement, the proposed method for recordkeeping and maintaining records for 3 years is unrealistic.

I would urge you to seriously reconsider passing this proposed regulation.

Respectfully yours,

Deborah A. Hass, Pharm.D., BCOP
Hematology/Oncology Clinical Pharmacist
Stanford Hospitals and Clinics
300 Pasteur Drive
Room H0301, M/C 5616
Stanford, CA. 94305
Central Pharmacy Phone: 650-723-5970
Central Pharmacy Fax: 650-725-5028
Satellite Pharmacy Phone: 650-725-5299
Pager: 650-723-8222 ID 16045
E-mail: DHass@stanfordmed.org <mailto:DHass@stanfordmed.org>

"Sloan, Steve"
<steve.sloan@cpspharm.com
>

09/10/2008 09:27 AM

To <karen_cates@dca.ca.gov>
cc
bcc
Subject Board of Pharmacy

Dear Ms. Cates,

This is intended to state our concerns about proposed compounding regulations by the Board of Pharmacy. The proposed regulations do not take into consideration emergency situations where the additional logging and labeling requirements will be burdensome and cause delays in therapy. Our position, and that of the California Society of Health-System Pharmacists, is that these requirements do not improve patient safety because the dose is administered immediately after compounding. Please make an exception for emergency use.

Karen Nishi
Director - Regulatory Affairs
3750 Torrey View Court
San Diego, CA 92130
858.617.5966 tel
karen.nishi@cardinal.com

2008 SEP 15 PM 3:28

CardinalHealth

September 12, 2008

California State Board of Pharmacy
Attn: Ms. Karen Cates
1625 North Market Boulevard
N219
Sacramento, CA 95834
karen_cates@dca.ca.gov

RE: 16 CCR § 1735.3 Records of Compounded Drug Products - Proposed Compounding Regulations; Request for Comments

Dear Ms. Cates:

Cardinal Health commends and supports the Board of Pharmacy for their efforts to improve patient safety by strengthening the regulations surrounding compounding. We would like to offer our comments and suggestions regarding the proposed regulations for pharmacies that compound and provide sterile injectable preparations. We appreciate the efforts of the Board of Pharmacy committee who wrote the initial draft of the proposed rules and we have attempted to use the framework they created in making our suggested changes to the rules.

Suggestions for changes to the general language:

Since the proposed regulations are for compounded medications, we believe the term "expiration date" should be changed to "beyond use date" to better track with the language used by the United States Pharmacopeia (USP) and the Joint Commission.

References to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) should be updated to the Joint Commission.

The National Institute for Occupational Safety and Health (NIOSH) and the Joint Commission often refer to "cytotoxic agents" and "chemotherapy" as "hazardous drugs".

16 CCR § 1735.3 – Records of Compounded Drug Products

This section details the pharmacy record requirements for each compounded drug product. The section does not differentiate between routine scheduled drug products and those injectables prepared for stat or immediate use. We would agree that information such as the master formula, the date compounded, identifiers of who compounded and checked the product, as well as the quantity of each component are essential. However, documenting data elements indicating the supplier, lot number, equipment used, assigned pharmacy reference number and "expiration date" may slow the preparation and delivery of emergency medications. The latest USP Chapter 797 has a special section related to "Immediate Use Compounded Sterile Products" which supports the distinction from a scheduled administration. We believe the Board could follow the same path as USP 797 by delineating fewer record keeping requirements for injectables prepared for immediate patient administration.

We would like to suggest the following provision be added to the proposed regulations:

§ 1735.3 Records of Compounded Drug Products
(e) Immediate use injectable products needed for stat or emergency patient administration will be exempt from 6-9 above.

By recognizing the difference between a stat life saving administration and a non-urgent one, pharmacists can provide the appropriate patient care and comply with the necessary record keeping requirements.

If you have any additional questions, please feel free to contact me at (858) 617-5966 or e-mail at karen.nishi@cardinalhealth.com. On behalf of Cardinal Health, we thank you for considering our comments and the efforts the Board has made in drafting the proposed regulations.

Sincerely,

Karen Nishi

Karen Nishi
Director of Regulatory Affairs

cc: Jack Coffey

"Miller, Ray - SFMH"
<Ray.Miller@chw.edu>
09/15/2008 05:39 PM

To <karen_cates@dca.ca.gov>
cc <philip@cshp.org>, "Yee, William - SJMC" <William.Yee@chw.edu>
bcc
Subject Proposed Compounding Regulations

Dear Ms. Cates:

The CSHP has alerted hospital pharmacists that the BOP is considering amending the California Code of Regulations by adding and/or amending sections 1735 thru 1751.8 of Division 17 of Title 16..

A careful reading of the proposed language does not make it clear to me whether it is the intention of the BOP to include hospital pharmacies who compound admixtures for immediate use on inpatients in these changes. The proposed self assessment that was distributed is titled "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" which implies that it is not intended for hospitals that are accredited by TJC.

Please make sure that the language of these revisions makes it clear that hospital pharmacies accredited by TJC are not bound by these provisions. Although, we comply with many of the quality initiative suggested, the volume of work done in a hospital, as well as the immediate nature of our work would make it difficult to comply with any requirement that every ingredient's lot number, manufacturer etc. be recorded.

Thank you for your consideration.

Ray Miller, Pharm. D.
Director of Pharmacy
St. Francis Memorial Hospital
900 Hyde Street
San Francisco, Ca 94109
(415) 353-6451

"Hendrick, Lynn"
<Lynn.Hendrick@chomp.org>

09/16/2008 10:26 AM

To <karen_cates@dca.ca.gov>
cc <philip@cshp.org>
bcc
Subject Proposed changes for medication compounding

September 16, 2008

Dear State Board of Pharmacy and Karen Cates,

I have reviewed the proposed changes to regulations for medication compounding, including:

* Master formula must be in writing and to include QA required and expiration date requirement for each product compounded.
* Labeling must include a statement that the product was compounded by the pharmacy; pharmacy reference number or lot number must be provided for each dispensed IV.
* Chemotherapy labeling must include "Chemotherapy - Dispose of Properly"
* Pharmacy Logs must include date, personnel, each ingredient (drug, dose, manufacturer and lot #), equipment used, pharmacy reference or lot number, expiration date, quantity, etc. for each compounded product.
* Records of all supplies and ingredients purchased, used or destroyed are maintained.
* All records and logs are maintained for a minimum of 3 years.
* Written policies/procedures reviewed annually and to include procurement of ingredients/supplies, methodology of compounding, personnel training, competency, equipment/facilities, cleaning, quality assurance, recall process, communication of changes, methodology of determining expiration dating, etc.
* Limits supply to MD offices to 72 hour supply of compounded medications.

Sterile Injectable Compounding Changes (in addition to those above)

* Written policies/procedures on disposal of infectious materials and cytotoxics.
* Labeling of each compounded product to include route and rate of administration.
* Quality Assurance to include sterility testing of any batch prepared products.

I have some serious concerts pertaining to the proposed changes for medication compounding regulations, specifically with IV medications preparation and the urgent needs of some of these medications. I would ask for an exemption of logging and pharmacy lot number assignment/labeling for those "immediate use" products as defined by USP. These products are needed urgently and there is a potential of delay with the additional record keeping requirements with no benefit to the patient. Any future recall of product would be moot as the IV would be already administered as an immediate-use.

It is unreasonable to think that every STAT alteplase, epinephrine, diltiazem or other life-saving medication prepared by a pharmacist during cardiac resuscitation, in the emergency department, in the operating rooms or in other critical care areas would be delayed a few minutes longer to assure logging, assignment, and labeling of the IV bag with a pharmacy lot number.

In addition, for all products, whether STAT or non-urgent, extensive recordkeeping would be required for each product prepared and maintained for a minimum of 3 years. Considering the hundreds (or in some larger hospitals, thousands) of records daily that would be generated to meet the requirement, the proposed method for recordkeeping and maintaining records for 3 years is unrealistic and wasteful.

Thank you for your consideration,

Lynn Hendrick, PharmD
Clinical Pharmacist at the Community Hospital of the Monterey Peninsula
Confidentiality Notice:
This is a transmission from Community Hospital of the Monterey Peninsula. This message and any attached documents may be confidential and contain information protected by state and federal medical privacy statutes. They are intended only for the use of the addressee. If you are not the intended recipient, any disclosure, copying, or distribution of this information is strictly prohibited. If you received this transmission in error, please accept our apologies and notify the sender.

Thank you.

CSHP | CALIFORNIA SOCIETY OF HEALTH-SYSTEM PHARMACISTS
Partners in Medication Management

September 16, 2008

Virginia Herold
Executive Officer
California Board of Pharmacy
1625 N. Market Blvd N219
Sacramento, California 95834
Virginia_Herold@dca.ca.gov

Re: Proposed Requirements for Pharmacies that Compound Medications

Dear Ms. Herold:

The California Society of Health-System Pharmacists (CSHP) commends and supports the California Board of Pharmacy (board) for their previous and current efforts to strengthen the regulations surrounding pharmacies that compound medications. However, CSHP has concerns regarding sections of the proposed compounding regulations that pertain to new labeling and pharmacy record requirements with regard to certain compounded IV medications that would inevitably delay treatment to the direst of patients.

It is common practice for a pharmacy in an acute care facility to prepare emergency compounded medications for the treatment of heart attack, stroke, and other life-threatening situations. Such patients require ***one-time and immediate-use (STAT) medications***, such as alteplase, epinephrine, or diltiazem for treatment. CSHP members are concerned that the added documentation requirements for both the label and pharmacy log will delay the preparation and delivery of these one-time and immediate-use medications; therefore, placing the patient at risk without any additional benefit to patient safety and care.

CSHP fails to see the advantage in delaying treatment for patients with critical conditions to record the pharmacy reference number or lot number on the label of each dispensed IV and the additional information in the pharmacy log when such labeling and recordkeeping requirements are primarily intended to be used in the event of a medication recall. CSHP believes that such information would be obsolete in situations where patients are in need of one-time and immediate-use compounded products as any future recall of these products would be moot as the IV would be already administered to the patient.

As the proposed regulations stand now, every STAT compounded medication with life-saving potential prepared by a pharmacist during cardiac resuscitation, in the emergency department, in the operating rooms, or in other critical care areas would be delayed a few minutes longer to assure logging, assignment, and labeling of the IV bag with a pharmacy lot number.

Exempting immediate-use and one-time sterile products from some regulations has been done before. The recently updated United States Pharmacopeial Convention (USP) Chapter 797 has a special section related to *Immediate-Use Compounded Sterile Products* as the immediate-use provision is intended only

for those situations where there is a need for emergency or immediate patient administration of a compounded product.

As it relates to the preparation of one-time and immediate–use injectable products in acute care facilities, ***CSHP requests all proposed additional pharmacy record requirements be exempted from the pharmacy records. CSHP also requests an exemption of having to record the pharmacy reference number or lot number on the label for one-time and immediate-use IV medications.*** CSHP believes that an exemption from additional record keeping requirements would be best to ensure that patients in acute care facilities with one-time and immediate-use needs are treated in a safe and appropriate timeframe.

These exemptions in STAT situations will certainly benefit and prolong patients' lives as they receive compounded medications urgently. CSHP hopes the following suggestions will help to meet our shared goal of better and safer patient care, and appreciate the board's willingness to consider our requests.

Founded in 1962, CSHP is a professional society representing more than 4,000 pharmacists, pharmacy technicians, and associates who serve patients and the public by promoting wellness and the best use of medications. CSHP members practice in a variety of organized health care settings including, but not limited to hospitals, integrated healthcare systems, clinics, home health care and ambulatory settings.

If you have any questions, please do not hesitate to contact me at (916) 447-1033 or CSHP's Legislative Advocate Bryce Docherty at (916) 446-4343.

Respectfully,

Dawn Benton
Executive Vice President, CEO

cc. Bryce Docherty

"Hayashi, Joanne S"
<Joanne.Hayashi@chomp.org>
09/16/2008 12:54 PM

To <karen_cates@dca.ca.gov>
cc <philip@cshp.org>
bcc
Subject FW: Proposed changes for medication compounding

September 16, 2008

Dear State Board of Pharmacy and Karen Cates,

I have reviewed the proposed changes to regulations for medication compounding, including:

* Master formula must be in writing and to include QA required and expiration date requirement for each product compounded.
* Labeling must include a statement that the product was compounded by the pharmacy; pharmacy reference number or lot number must be provided for each dispensed IV.
* Chemotherapy labeling must include "Chemotherapy - Dispose of Properly"
* Pharmacy Logs must include date, personnel, each ingredient (drug, dose, manufacturer and lot #), equipment used, pharmacy reference or lot number, expiration date, quantity, etc. for each compounded product.
* Records of all supplies and ingredients purchased, used or destroyed are maintained.
* All records and logs are maintained for a minimum of 3 years.
* Written policies/procedures reviewed annually and to include procurement of ingredients/supplies, methodology of compounding, personnel training, competency, equipment/facilities, cleaning, quality assurance, recall process, communication of changes, methodology of determining expiration dating, etc.
* Limits supply to MD offices to 72 hour supply of compounded medications.

Sterile Injectable Compounding Changes (in addition to those above)

* Written policies/procedures on disposal of infectious materials and cytotoxics.
* Labeling of each compounded product to include route and rate of administration.
* Quality Assurance to include sterility testing of any batch prepared products.

I have some serious concerns pertaining to the proposed changes for medication compounding regulations, specifically with IV medications preparation and the urgent needs of some of these medications. I would ask for an exemption of logging and pharmacy lot number assignment/labeling for those "immediate use" products as defined by USP. These products are needed urgently and there is a potential of delay with the additional record keeping requirements with no benefit to the patient. Any future recall of product would be moot as the IV would be already administered as an immediate-use.

It is unreasonable to think that every STAT alteplase, epinephrine, diltiazem or other life-saving medication prepared by a pharmacist during cardiac resuscitation, in the emergency department, in the operating rooms or in other critical care areas would be delayed a few minutes longer to assure logging, assignment, and labeling of the IV bag with a pharmacy lot number.

In addition, for all products, whether STAT or non-urgent, extensive recordkeeping would be required for each product prepared and maintained for a minimum of 3 years. Considering the hundreds (or in some larger hospitals, thousands) of records daily that would be generated to meet the requirement, the proposed method for recordkeeping and maintaining records for 3 years is unrealistic and wasteful. It may also compromise patient safety since the focus will be shifted from the real task at hand - safe, aseptic compounding of CSPs to the task of record keeping!!

Thank you for your consideration,

Joanne Hayashi, PharmD
Clinical Pharmacist at the Community Hospital of the Monterey Peninsula
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Thank you.

"Chopyk, Rob"
<Rob.Chopyk@chomp.org>
09/16/2008 02:07 PM

To <karen_cates@dca.ca.gov>
cc <philip@cshp.org>
bcc
Subject

September 16, 2008

Dear State Board of Pharmacy and Karen Cates,

I have reviewed the proposed changes to regulations for medication compounding, including:

* Master formula must be in writing and to include QA required and expiration date requirement for each product compounded.
* Labeling must include a statement that the product was compounded by the pharmacy; pharmacy reference number or lot number must be provided for each dispensed IV.
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* Limits supply to MD offices to 72 hour supply of compounded medications.

Sterile Injectable Compounding Changes (in addition to those above)

* Written policies/procedures on disposal of infectious materials and cytotoxics.
* Labeling of each compounded product to include route and rate of administration.
* Quality Assurance to include sterility testing of any batch prepared products.

I have some serious concerns pertaining to the proposed changes for medication compounding regulations, specifically with IV medications preparation and the urgent needs of some of these medications. I would ask for an exemption of logging and pharmacy lot number assignment/labeling for those "immediate use" products as defined by USP. These products are needed urgently and there is a potential of delay with the additional record keeping requirements with no benefit to the patient. Any future recall of product would be moot as the IV would be already administered as an immediate-use.

It is unreasonable to think that every STAT alteplase, epinephrine, diltiazem or other life-saving medication prepared by a pharmacist during cardiac resuscitation, in the emergency department, in the operating rooms or in other critical care areas would be delayed a few minutes longer to assure logging, assignment, and labeling of the IV bag with a pharmacy lot number.

In addition, for all products, whether STAT or non-urgent, extensive recordkeeping would be required for each product prepared and maintained for a minimum of 3 years. Considering the hundreds (or in some larger hospitals, thousands) of records daily that would be generated to meet the requirement, the proposed method for recordkeeping and maintaining records for 3 years is unrealistic and wasteful.

Thank you for your consideration,

Rob Chopyk RPh
Clinical Pharmacist
Community Hospital of the
Monterey Peninsula
(831) 625-4905

North Coast Society of Health-System Pharmacists

C/O
Michael W. Sanders, Chapter President
128 Alderbrook Drive
Santa Rosa, CA 95405-4602
(707) 545-0742

September 15, 2008

Board of Pharmacy
Attn: Karen Cates (Proposed Compounding Regulation)
1625 N. Market Blvd. N219
Sacramento, CA 95834
Fax: (916) 574-8618

RE: Proposed changes to 16-CCR 1716.1 and 1716.2

Dear Karen,

On behalf of the members of our C.S.H.P-affiliated chapter, I wish to voice my objection to certain language changes or omissions pertaining to your proposed revisions to these regulations.

Health system pharmacies, especially in hospitals, must prepare numerous 'stat' or 'now' compounded IV and other products for acutely ill patients. Without exempting immediate or one time use compounded products from §1735.1, Compounding Definitions, the board is placing unreasonable and unnecessary recordkeeping and labeling requirements on already overburdened health care systems in California.

We pharmacists and pharmacy technicians of the North Coast Chapter of C.S.H.P. therefore ask you to rescind these regulatory changes without first making accommodation for immediate and one time use compounded products. Your affirmative action in response would be much appreciated.

Michael W. Sanders, Pharm.D. President, North Coast Society of Health-System Pharmacists
CC: 1) Board of Directors, 2) CSHP, 3) File

"Yi, Man"
<Man.Yi@chomp.org>
09/17/2008 09:10 AM

To <karen_cates@dca.ca.gov>
cc <philip@cshp.org>
bcc
Subject Proposed changes for medication compounding

September 17, 2008

Dear State Board of Pharmacy and Karen Cates,

I have reviewed the proposed changes to regulations for medication compounding, including:

* Master formula must be in writing and to include QA required and expiration date requirement for each product compounded.
* Labeling must include a statement that the product was compounded by the pharmacy; pharmacy reference number or lot number must be provided for each dispensed IV.
* Chemotherapy labeling must include "Chemotherapy - Dispose of Properly"
* Pharmacy Logs must include date, personnel, each ingredient (drug, dose, manufacturer and lot #), equipment used, pharmacy reference or lot number, expiration date, quantity, etc. for each compounded product.
* Records of all supplies and ingredients purchased, used or destroyed are maintained.
* All records and logs are maintained for a minimum of 3 years.
* Written policies/procedures reviewed annually and to include procurement of ingredients/supplies, methodology of compounding, personnel training, competency, equipment/facilities, cleaning, quality assurance, recall process, communication of changes, methodology of determining expiration dating, etc.
* Limits supply to MD offices to 72 hour supply of compounded medications.

Sterile Injectable Compounding Changes (in addition to those above)

* Written policies/procedures on disposal of infectious materials and cytotoxics.
* Labeling of each compounded product to include route and rate of administration.
* Quality Assurance to include sterility testing of any batch prepared products.

"I have some serious concerns pertaining to the proposed changes for medication compounding regulations, specifically with IV medications preparation and the urgent needs of some of these medications. I would ask for an exemption of logging and pharmacy lot number assignment/labeling for those "immediate use" products as defined by USP. These products are needed urgently and there is a potential of delay with the additional record keeping requirements with no benefit to the patient. Any future recall of product would be moot as the IV would be already administered as an immediate-use.

It is unreasonable to think that every STAT alteplase, epinephrine, diltiazem or other life-saving medication prepared by a pharmacist during cardiac resuscitation, in the emergency department, in the operating rooms or in other critical care areas would be delayed a few minutes longer to assure logging, assignment, and labeling of the IV bag with a pharmacy lot number.

In addition, for all products, whether STAT or non-urgent, extensive recordkeeping would be required for each product prepared and maintained for a minimum of 3 years. Considering the hundreds (or in some larger hospitals, thousands) of records daily that would be generated to meet the requirement, the proposed method for recordkeeping and maintaining records for 3 years is unrealistic and wasteful."

I totally agree with my colleague's concerns above.
Thank you for your consideration,

Man Yi
R.ph, MS.
Clinical Pharmacist at the Community Hospital of the Monterey Peninsula

"Fukano, Robert"
<Robert.Fukano@chomp.org
>
09/17/2008 03:08 PM

To <karen_cates@dca.ca.gov>
cc <philip@cshp.org>
bcc
Subject

Dear State Board of Pharmacy and Karen Cates,

I have reviewed the proposed changes to regulations for medication compounding, including:

* Master formula must be in writing and to include QA required and expiration date requirement for each product compounded.
* Labeling must include a statement that the product was compounded by the pharmacy; pharmacy reference number or lot number must be provided for each dispensed IV.
* Chemotherapy labeling must include "Chemotherapy - Dispose of Properly"
* Pharmacy Logs must include date, personnel, each ingredient (drug, dose, manufacturer and lot #), equipment used, pharmacy reference or lot number, expiration date, quantity, etc. for each compounded product.
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* Written policies/procedures reviewed annually and to include procurement of ingredients/supplies, methodology of compounding, personnel training, competency, equipment/facilities, cleaning, quality assurance, recall process, communication of changes, methodology of determining expiration dating, etc.
* Limits supply to MD offices to 72 hour supply of compounded medications.

Sterile Injectable Compounding Changes (in addition to those above)

* Written policies/procedures on disposal of infectious materials and cytotoxics.
* Labeling of each compounded product to include route and rate of administration.
* Quality Assurance to include sterility testing of any batch prepared products.

I have some serious concerns pertaining to the proposed changes for medication compounding regulations, specifically with IV medications preparation and the urgent needs of some of these medications. I would ask for an exemption of logging and pharmacy lot number assignment/labeling for those "immediate use" products as defined by USP. These products are needed urgently and there is a potential of delay with the additional record keeping requirements with no benefit to the patient. Any future recall of product would be moot as the IV would be already administered as an immediate-use.

It is unreasonable to think that every STAT alteplase, epinephrine, diltiazem or other life-saving medication prepared by a pharmacist during cardiac resuscitation, in the emergency department, in the operating rooms or in other critical care areas would be delayed a few minutes longer to assure logging, assignment, and labeling of the IV bag with a pharmacy lot number.

In addition, there are dozens of hospital in California without 24 hour pharmacy services in which nurses are compounding and mix intravenous products

without the aid of any sterile preparation area or laminar flow hood/biological safety cabinet. Why the separation of record-keeping of pharmacy-prepared versus nurse-prepared or physician-prepared (thinking of anesthesiologists who prepare medication in the operating room)?

In addition, for all products, whether STAT or non-urgent, extensive recordkeeping would be required for each product prepared and maintained for a minimum of 3 years. Considering the hundreds (or in some larger hospitals, thousands) of records daily that would be generated to meet the requirement, the proposed method for recordkeeping and maintaining records for 3 years is unrealistic and wasteful.

Thank you for your consideration,

Robert M. Fukano, PharmD
Intensive Care Unit/Critical Care Unit Clinical Pharmacist
Community Hospital of the Monterey Peninsula
Monterey, California

"Berger, Alex \(OCH\)"
<AlexBerger@dochs.org>
09/18/2008 09:48 PM

To <karen_cates@dca.ca.gov>
cc
bcc
Subject Action Requested: New Compound Sterile Injectable Products Regulations

Hello Karen Cates,

This is a TERRIBLE new regulation that will jeopardize patient's care! We do not have time to for more documentation when an IV medication is needed STAT. STAT means medication is needed now, or the patient will die.

This regulation should exempt IVs for immediate /STAT administration.

Alexander Berger,

Staff pharmacist O'Connor Hospital,San Jose

"Jones, Kimberly J"
<Kimberly.Jones@chomp.org>

09/20/2008 11:00 AM

To <karen_cates@dca.ca.gov>
cc <philip@cshp.org>
bcc
Subject Proposal for medication compounding

September 20, 2008

Dear State Board of Pharmacy and Karen Cates,

I have reviewed the proposed changes to regulations for medication compounding, including:

* Master formula must be in writing and to include QA required and expiration date requirement for each product compounded.
* Labeling must include a statement that the product was compounded by the pharmacy; pharmacy reference number or lot number must be provided for each dispensed IV.
* Chemotherapy labeling must include "Chemotherapy - Dispose of Properly"
* Pharmacy Logs must include date, personnel, each ingredient (drug, dose, manufacturer and lot #), equipment used, pharmacy reference or lot number, expiration date, quantity, etc. for each compounded product.
* Records of all supplies and ingredients purchased, used or destroyed are maintained.
* All records and logs are maintained for a minimum of 3 years.
* Written policies/procedures reviewed annually and to include procurement of ingredients/supplies, methodology of compounding, personnel training, competency, equipment/facilities, cleaning, quality assurance, recall process, communication of changes, methodology of determining expiration dating, etc.
* Limits supply to MD offices to 72 hour supply of compounded medications.

Sterile Injectable Compounding Changes (in addition to those above)

* Written policies/procedures on disposal of infectious materials and cytotoxics.
* Labeling of each compounded product to include route and rate of administration.
* Quality Assurance to include sterility testing of any batch prepared products.

I have some serious concerns pertaining to the proposed changes for medication compounding regulations, specifically with IV medications preparation and the urgent needs of some of these medications. I would ask for an exemption of logging and pharmacy lot number assignment/labeling for those "immediate use" products as defined by USP. These products are needed urgently and there is a potential of delay with the additional record keeping requirements with no benefit to the patient. Any future recall of product would be moot as the IV would be already administered as an immediate-use.

It is unreasonable to think that every STAT alteplase, epinephrine, diltiazem or other life-saving medication prepared by a pharmacist during cardiac resuscitation, in the emergency department, in the operating rooms or in other critical care areas would be delayed a few minutes longer to assure logging, assignment, and labeling of the IV bag with a pharmacy lot number.

In addition, for all products, whether STAT or non-urgent, extensive recordkeeping would be required for each product prepared and maintained for a minimum of 3 years. Considering the hundreds (or in some larger hospitals, thousands) of records daily that would be generated to meet the requirement, the proposed method for recordkeeping and maintaining records for 3 years is unrealistic and wasteful.

Thank you for your consideration,

Kimberly Jones, PharmD
Clinical Pharmacist at the Community Hospital of the Monterey Peninsula
Confidentiality Notice:
This is a transmission from Community Hospital of the Monterey Peninsula. This message and any attached documents may be confidential and contain information protected by state and federal medical privacy statutes. They are intended only for the use of the addressee. If you are not the intended recipient, any disclosure, copying, or distribution of this information is strictly prohibited. If you received this transmission in error, please accept our apologies and notify the sender.

Thank you.

"Naidu, Dharma R"
<Dharma.Naidu@chomp.org>

09/24/2008 07:28 AM

To <karen_cates@dca.ca.gov>
cc <philip@cshp.org>
bcc
Subject FW: Proposed changes for medication compounding

September 16, 2008

Dear State Board of Pharmacy and Karen Cates,

I have reviewed the proposed changes to regulations for medication compounding, including:

* Master formula must be in writing and to include QA required and expiration date requirement for each product compounded.
* Labeling must include a statement that the product was compounded by the pharmacy; pharmacy reference number or lot number must be provided for each dispensed IV.
* Chemotherapy labeling must include "Chemotherapy - Dispose of Properly"
* Pharmacy Logs must include date, personnel, each ingredient (drug, dose, manufacturer and lot #), equipment used, pharmacy reference or lot number, expiration date, quantity, etc. for each compounded product.
* Records of all supplies and ingredients purchased, used or destroyed are maintained.
* All records and logs are maintained for a minimum of 3 years.
* Written policies/procedures reviewed annually and to include procurement of ingredients/supplies, methodology of compounding, personnel training, competency, equipment/facilities, cleaning, quality assurance, recall process, communication of changes, methodology of determining expiration dating, etc.
* Limits supply to MD offices to 72 hour supply of compounded medications.

Sterile Injectable Compounding Changes (in addition to those above)

* Written policies/procedures on disposal of infectious materials and cytotoxics.
* Labeling of each compounded product to include route and rate of administration.
* Quality Assurance to include sterility testing of any batch prepared products.

I have some serious concerns pertaining to the proposed changes for medication compounding regulations, specifically with IV medications preparation and the urgent needs of some of these medications. I would ask for an exemption of logging and pharmacy lot number assignment/labeling for those "immediate use" products as defined by USP. These products are needed urgently and there is a potential of delay with the additional record keeping requirements with no benefit to the patient. Any future recall of product would be moot as the IV would be already administered as an immediate-use.

It is unreasonable to think that every STAT alteplase, epinephrine, diltiazem or other life-saving medication prepared by a pharmacist during cardiac resuscitation, in the emergency department, in the operating rooms or in other critical care areas would be delayed a few minutes longer to assure logging, assignment, and labeling of the IV bag with a pharmacy lot number.

In addition, for all products, whether STAT or non-urgent, extensive recordkeeping would be required for each product prepared and maintained for a minimum of 3 years. Considering the hundreds (or in some larger hospitals, thousands) of records daily that would be generated to meet the requirement, the proposed method for recordkeeping and maintaining records for 3 years is unrealistic and wasteful.

Thank you for your consideration,

Dharma Naidu, Pharm.D
Pharmacy Supervisor
Community Hospital of the Monterey Peninsula
P Please consider the environment before printing this e-mail
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Thank you.

Catholic Healthcare West
CHW

September 26, 2008

Virginia Herold
Executive Officer
California Board of Pharmacy
1625 N. Market Blvd N219
Sacramento, California 95834
Virginia_Herold@dca.ca.gov

Re: Proposed Requirements for Pharmacies that Compound Medications

Dear Ms. Herold:

On behalf of 34 of our hospitals in California, Catholic Healthcare West (CHW) appreciates the opportunity to provide comment on the proposed requirements for pharmacies that compound medications. As California's largest non-profit hospital system, we are committed to our mission of providing compassionate, high quality healthcare to all.

While CHW supports the California Board of Pharmacy (Board) for its efforts to strengthen regulations for pharmacies that compound medications, we have serious concerns regarding the new labeling and pharmacy record requirements on certain compounded IV medications, particularly for pharmacies in acute care facilities dispensing one-time and immediate-use (STAT) medications.

Pharmacies in acute care facilities are charged with the timely preparation of emergency compounded medications for the treatment of conditions that require quick treatment and response, such as heart attack, stroke, and other life-threatening situations. These conditions require STAT medications, such as alteplase, epinephrine, or diltiazem for treatment. **CHW is concerned the added documentation requirements will delay preparation and delivery, placing patients at risk for no additional patient safety benefit.**

CHW sees the value of documenting pharmacy reference numbers or lot numbers on the label of each dispensed IV as well as providing additional information in the pharmacy log when such labeling and recordkeeping requirements are primarily intended to be used in the event of a medication recall. However, CHW suggests this information is not useful when the medication is dispensed on a one-time, immediate-use basis. **CHW urges the Board to exempt one-time, immediate-use sterile products in the final regulation, including the requirement to provide:**

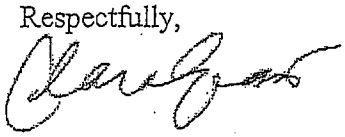
- **The manufacturer or supplier and lot number or each component;**
- **The equipment used in compounding the drug product;**
- **The pharmacy assigned reference or lot number for the compounded drug product; and,**
- **The expiration date of the final compounded drug product.**

There is some president to exempting STAT products from pharmaceutical regulations. In fact, in the recently updated United States Pharmacopeial Convention (USP) Chapter 797, there is a section related to *Immediate-Use Compounded Sterile Products*. In this section, these types of products are considered under separate requirements because they are used in situations where there is a need for emergency or immediate patient administration of a compounded product.

Finally, CHW is concerned the minimum 3-year record retention policy is unrealistic, considering the hundreds or thousands of products compounded daily, whether STAT or non-urgent. **CHW requests this timeframe be reevaluated and take into account common record retention policies.**

Thank you for your consideration of these comments. Please feel free to contact me at (916) 851-2007 or via email at Clara.Evans@chw.edu.

Respectfully,



Clara E. Evans
Director, Public Policy & Fiscal Advocacy

Board of Pharmacy
Attention: Karen Cates (Proposed compounding regulations)
1625 Market Blvd. N219.
Sacramento, Ca 95834

September 27, 2008

Dear Board of Pharmacy,

I am writing as a pharmacist with a 27-year history in the practice of Hospital Pharmacy. I am writing to pass along my strong opposition to your proposed compounding regulations, which, if not edited or clarified would have a significant negative impact on established pharmacy practice.

The standard of practice in hospital pharmacy for preparing IV admixtures is one that has been refined and continually updated by the pharmacy profession. Most recently, the extensive changes of the USP 797 requirements have further defined and altered the hospital pharmacy practice of preparing IV admixtures. The major problem with the proposed regulations by the Board of Pharmacy is the definition and distinction of what is considered a compounded item. It is my strong belief, and one I believe is shared by anyone in the hospital pharmacy profession, is that IV admixture preparation practice should be not bundled in with compounded prescriptions, such as topical, oral, or injectables compounded from non-sterile product or intended for sale or distribution to a patient or provider.

The most significant problem is with regulations 1735.3 and 1751.1 – the proposed recordkeeping regulations and they should NOT be passed. If the regulations are passed as proposed, and the intent is to apply it to all IV admixtures prepared in a hospital pharmacy environment, it would be a recordkeeping nightmare. The majority of IV admixtures prepared in the hospital setting fall within the low to medium risk category as well defined and described by USP 797. If for every IV admixture prepared the Board would expect to see LOT #, manufacturer, equipment used, personnel identity, pharmacist identity, pharmacy lot number, expiration dating, quantity, etc as described in 1735.3, the treatment of acutely ill patients would be at risk. Even in a small, rural critical access hospital we often mix over 100 IV admixtures in a day. In a larger institution, this number would be 10-20 times higher and the recordkeeping requirements, which the regulations imply, would be overwhelming and create an enormous burden on pharmacy professionals. Furthermore, I believe this extensive recordkeeping would not significantly improve medication or patient safety.

I strongly recommend that you **do not pass** the proposed regulations as they are currently written and you evaluate the intent of the regulations for all aspects of professional pharmacy practice. Specifically, please consider the recommendations and consultation of pharmacy professionals within hospital pharmacy practice and how the "sterile compound" regulations pertain to the practice of IV admixture services.

In addition to the above considerations, please reconsider the language of 1751.5, 1751.6 and 1751.7. It would seem prudent to follow the practice guidelines for USP 797 in the areas such as training, cleaning, garbing, and quality assurance as these standards have reviewed by a group of nationally recognized individuals.

Thank you for your consideration of this letter.

Sincerely,

Lois F. Leister, RPh, M.S., M.B.A.
Practicing hospital pharmacist, Member of CSHP
29930 Sherwood Road
Fort Bragg, CA 95437
Email lfander@mcn.org

"David F. Elder"
<DElder@skdh.org>
09/29/2008 02:40 PM

To <karen_cates@dca.ca.gov>
cc
bcc
Subject Compounding Regulations

To The California Board of Pharmacy:

I agree with CSHP's concerns below. We already keep adequate records of compounded items in our logs. Items that must be used immediately in a code or other emergency are also documented adequately on the patients profile.....keeping records for 3 years and generating all the policies required below is not necessary, since compounding skills already are defined and this is tedious work that does not do anything to protect the patient, rather, all the labeling will adversely affect our patients. In addition to CSHP's concerns, I have placed my comments below. I also agree with the concerns of CSHP in addition to mine!

Thank you for considering my point of view. I do not agree with the Board on this issue.

David Elder, PharmD
Director of Pharmacy Services
Sierra Kings District Hospital
372 W. Cypress Ave.
Reedley, CA 93654
(559) 638-8155 Ext. **334**
(559) 637-7556 (FAX)
(559) 707-5143 (CELL)
delder@skdh.org

All compounding (each prescription vial/product or IV medication)

- Master formula must be in writing and to include QA required and expiration date requirement for each product compounded.
- Labeling must include a statement that the product was compounded by the pharmacy; **pharmacy reference number or lot number must be provided for each dispensed IV.**
- Chemotherapy labeling must include "Chemotherapy - Dispose of Properly"
- **Pharmacy Logs must include date, personnel, each ingredient (drug, dose, manufacturer and lot #), equipment used, pharmacy reference or lot number, expiration date, quantity, etc. for each compounded product.**
- Records of all supplies and ingredients purchased, used or destroyed are maintained.
- **All records and logs are maintained for a minimum of 3 years.**
- **Written policies/procedures reviewed annually and to include procurement of ingredients/supplies, methodology of compounding, personnel training, competency, equipment/facilities, cleaning, quality assurance, recall process, communication of changes,**

methodology of determining expiration dating, etc.

- Limits supply to MD offices to 72 hour supply of compounded medications.

*

Sterile Injectable Compounding Changes (in addition to those above) these items are already being done or are written in existing policies and on labels etc. This is just un-necessary duplication.....

- Written policies/procedures on disposal of infectious materials and cytotoxics.>>>>>>>*
- Labeling of each compounded product to include route and rate of administration.....*
- Quality Assurance to include sterility testing of any batch prepared products.....*

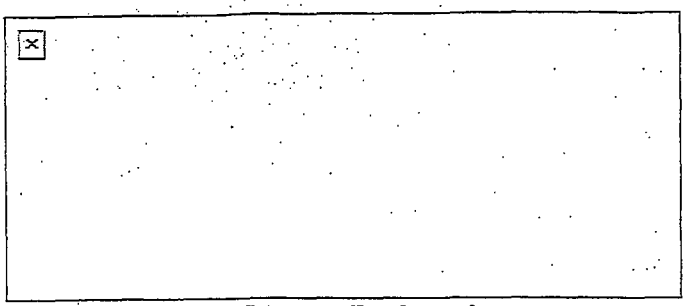
CSHP has concerns with the above underlined and bolded language as it pertains to IV medications and the urgent needs of some of these medications. **We have asked for an exemption of logging and pharmacy lot number assignment/labeling for those "immediate use" products as defined by USP. These products are needed urgently and there is a potential of delay with the additional record keeping requirements with no benefit to the patient. Any future recall of product would be moot as the IV would be already administered as an immediate-use.** Unfortunately, our concerns were not heard by the Board of Pharmacy and the proposed regulations have been posted without change. This means every STAT alteplase, epinephrine, diltiazem or other life-saving medication prepared by a pharmacist during cardiac resuscitation, in the emergency department, in the operating rooms or in other critical care areas would be delayed a few minutes longer to assure logging, assignment, and labeling of the IV bag with a pharmacy lot number.

In addition, for all products, whether STAT or non-urgent, extensive recordkeeping would be required for each product prepared and maintained for a minimum of 3 years. Considering the hundreds (or in some larger hospitals, thousands) of records daily that would be generated to meet the requirement, the proposed method for recordkeeping and maintaining records for 3 years is unrealistic.

This is just not necessary or practical???? Why would we want these fire hazards around so long, when we already generate enough flammable material in our storage areas????

David Elder, PharmD
Director of Pharmacy Services
Sierra Kings District Hospital
372 W. Cypress Ave.

Reedley, CA 93654
(559) 638-8155 Ext. **334**
(559) 637-7556 (FAX)
(559) 707-5143 (CELL)
delder@skdh.org



12401 Washington Boulevard
Whittier, California 90602-1099
(562) 698-0811
Hearing Impaired TDD (562) 696-9267

September 30, 2008

Virginia Herold
Executive Officer
California Board of Pharmacy
1625 N. Market Blvd. N219
Sacramento, California 958834

Re: Proposed Requirements for Pharmacies that Compound Medications

Dear Ms. Herold:

I have commended and supported the California Board of Pharmacy for their previous and current efforts to strengthen the regulations surrounding pharmacists that compound medications. However, I have concerns regarding sections of the proposed compounding regulations that pertain to new labeling and pharmacy record requirements with regard to compounded IV medications in acute care hospitals.

In the past, there has always been a clear distinction between prescription compounding and manufacturing. Trying to apply manufacturing practices to an acute care setting can seriously jeopardize the hospital pharmacist's ability to respond to the acute needs of their patients. Clearly, the workflow process to manufacturer in bulk versus the compounding of sterile products for individual patient prescriptions are distinctly different in their response time and the need for timely administration to the patient.

I would highly recommend that the Board accept the recommended changes of the California Society of Health-System Pharmacists or create a working group of practicing hospital pharmacists and create a safe and workable process that will insure the ability of the hospital pharmacists to be responsive and responsible to safe guarding the protection of the patient. Creating regulations that mandate the same practice in all pharmacy practice arenas does not serve the specific needs of all of our patients.

If you have any questions, please do not hesitate to contact me at (562) 698-0811, Extension 2804.

Respectfully,

Alan Y. Endo, Pharm. D.
Pharmacy Director
RPh 27276

MNikuta <mnikuta@aol.com>

09/30/2008 08:03 AM

To karen_cates@dca.ca.gov

cc

bcc

Subject Proposed Requirements for Pharmacies that Compound Medication

I have concerns regarding sections of the proposed compounding regulations that pertain to new labeling and pharmacy record requirements with regard to certain compounded IV medications that would inevitably delay treatment to the direst of patients.

It is common practice for a pharmacy in an acute care facility to prepare emergency compounded medications for the treatment of heart attack, stroke, and other life-threatening situations. Such patients require ***one-time and immediate-use (STAT) medications*** ; such as alteplase, epinephrine, or diltiazem for treatment. I am concerned that the added documentation requirements for both the label and pharmacy log will delay the preparation and delivery of these one-time and immediate-use medications; therefore, placing the patient at risk without any additional benefit to patient safety and care.

I fail to see the advantage in delaying treatment for patients with critical conditions to record the pharmacy reference number or lot number on the label of each dispensed IV and the additional information in the pharmacy log when such labeling and recordkeeping requirements are primarily intended to be used in the event of a medication recall. Such information would be obsolete in situations where patients are in need of one-time and immediate-use compounded products as any future recall of these products would be moot as the IV would be already administered to the patient.

As the proposed regulations stand now, every STAT compounded medication with life-saving potential prepared by a pharmacist during cardiac resuscitation, in the emergency department, in the operating rooms, or in other critical care areas would be delayed a few minutes longer to assure logging, assignment, and labeling of the IV bag with a pharmacy lot number.

Exempting immediate-use and one-time sterile products from some regulations has been done before. The recently updated United States Pharmacopeial Convention (USP) Chapter 797 has a special section related to *Immediate-Use Compounded Sterile Products* as the immediate-use provision is intended only for those situations where there is a need for emergency or immediate patient administration of a compounded product.

As it relates to the preparation of one-time and immediate–use injectable products in acute care facilities, I believe that an exemption from additional record keeping requirements would be best to ensure that patients in acute care facilities with one-time and immediate-use needs are treated in a safe and appropriate timeframe.

Sincerely,

Mary Noud-Ikuta, PharmD

Find phone numbers fast with the New AOL Yellow Pages!

Virginia
Herold/Pharmacy/DCANotes
09/30/2008 11:50 AM

To "Anne Sodergren" <anne_sodergren@dca.ca.gov>
cc
bcc
Subject Fw: BOP Compounding Reg Statement Letter - 9-15-08

****
Sent from Blackberry
Virginia Herold
"Harold Mathis"
----- Original Message -----

From: "Harold Mathis" [hjmathis@tds.net]
Sent: 09/30/2008 11:47 AM
To: <Virginia_Herold@dca.ca.gov>
Subject: BOP Compounding Reg Statement Letter - 9-15-08

September 10, 2008

Virginia Herold

Executive Officer

CaliforniaBoard of Pharmacy

1625 N. Market BlvdN219

Sacramento, California 95834

Virginia_Herold@dca.ca.gov

Re: Proposed Requirements for Pharmacies that Compound Medications

The following message accurately outlines a vital error / misunderstanding of the emergency practice of pharmacy in the acute hospital. Delays mandated under the proposed legislation WILL CAUSE LOSS OF LIVES!

Harold Mathis, Consultant Pharmacist, former Director of Pharmacies – Mercy Hospital, Denver, Colorado, Former Chairman of the Committee to Revise Pharmacy Regulations, Colorado.

Dear Ms. Herold:

The California Society of Health-System Pharmacists (CSHP) commends and supports the California Board of Pharmacy (board) for their previous and current efforts to strengthen the regulations surrounding pharmacies that compound medications. However, CSHPhas concerns regarding sections of the proposed compounding regulations that pertain to new labeling and pharmacy record requirements with regard to certain compounded IV medications that would inevitably delay treatment to the direst of patients.

It is common practice for a pharmacy in an acute care facility to prepare emergency compounded medicationsfor the treatment of heart attack, stroke, and other life-threatening situations. Such patients require ***one-time and immediate-use (STAT) medications*** ; such as alteplase, epinephrine, or diltiazemfor treatment. CSHP members are concerned that the added documentation requirements for both the label and pharmacy log will delay the preparation and delivery of these one-time and immediate-use medications; therefore, placing the patient at risk without any additional benefit to patient safety and care.

CSHP fails to see the advantage in delaying treatment for patients with critical conditions to record the pharmacy reference number or lot number on the label of each dispensed IV and the additional information in the pharmacy log when such labeling and recordkeeping requirements are primarily intended to be used in the event of a medication recall. CSHP believes that such information would be obsolete in situations where patients are in need of one-time and immediate-use compounded products as anyfuture recall of these products would be moot as the IV would be already administered to the patient.

As the proposed regulations stand now, every STATcompounded medication with life-saving potential prepared by a pharmacist during cardiac resuscitation, in the emergency department, in the operating rooms, or in other critical care areas would be delayed a few minutes longer to assure logging, assignment, and labeling of the IV bag with a pharmacy lot number.

Exempting immediate-use and one-time sterile products from some regulations has been done

before. The recently updated United States Pharmacopeial Convention (USP) Chapter 797 has a special section related to Immediate-Use Compounded Sterile Products as the immediate-use provision is intended only for those situations where there is a need for emergency or immediate patient administration of a compounded product.

As it relates to the preparation of one-time and immediate–use injectable products in acute care facilities, ***CSHP requests all proposed additional pharmacy record requirements be exempted from the pharmacy records. CSHP also requests an exemption of having to record the pharmacy reference number or lot number on the label for one-time and immediate-use IV medications.*** CSHP believes that an exemption from additional record keeping requirements would be best to ensure that patients in acute care facilities with one-time and immediate-use needs are treated in a safe and appropriate timeframe.

These exemptions in STATsituations will certainly benefit and prolong patients' lives as they receive compounded medications urgently. CSHP hopes the following suggestions will help to meet our shared goal of better and safer patient care, and appreciate the board's willingness to consider our requests.

Founded in 1962, CSHP is a professional society representing more than 4,000 pharmacists, pharmacy technicians, and associates who serve patients and the public by promoting wellness and the best use of medications. CSHP members practice in a variety of organized health care settings including, but not limited to hospitals, integrated healthcare systems, clinics, home health care and ambulatory settings.

If you have any questions, please do not hesitate to contact me at (916) 447-1033or CSHP's Legislative Advocate Bryce Dochertyat (916) 446-4343.

Respectfully,

[IMAGE]

Dawn Benton

Executive Vice President, CEO

cc. Bryce Docherty


- header.htm

"Bryan Carlson"
<BCARLSON@childrenscentralcal.org>
10/01/2008 06:55 PM

To <karen_cates@dca.ca.gov>
cc
bcc
Subject Title 16. Board of Pharmacy Comments

To the California Board of Pharmacy,

Concerning the proposed changes beginning with Section: 1716 Requirements for Pharmacies that Compound Medications, Children's Hospital of Central California Pharmacy Department would like to make the following comments. In order to accommodate the changes being made to the pharmacy law, we feel that a phase in period of 12 months be considered. This time would allow for the necessary budget and process changes to be made. Although the Board of Pharmacy feels that these changes will have little fiscal impact on pharmacy practice, we feel differently. With all of the regulations that we are currently facing from the DEA, DHS, JCAHO, USP797, and the Board of Pharmacy, simply reviewing and coordinating them can be a costly venture both on time and finances.

Secondly, we suggest placing some of the burden back on the manufacturing community. Standardization of barcoding technology to include lot numbers and expiration dates along with the NDC would facilitate the record keeping process.

Lastly, we would like clarification on what is meant by "equipment" in Section 1735.3 subsection (a) (7). Are you asking that every lot number of every syringe and every needle used in the compounding process be documented and stored? Please clarify your intent on this item as we feel that this would be very difficult to comply with.

We, as a Children's Hospital, already have a very complex system to manage. As regulations add to the complexity, risk for error increases. Although we agree that pharmacy practice needs to be monitored and regulated, please consider the comments of CSHP and others when making your decisions. We cannot delay or negatively impact patient care just to comply with a regulation that was not well thought out.

Thank you for your time and consideration.

Pharmacy Department
Children's Hospital Central California
9300 Valley Children's Place
Madera, California 93636-8762
(559) 353-5504

To: Karen Cates
California State Board Of Pharmacy

From: Margaret Bradshaw,R.Ph.
PO Box 836
Albion, Ca 95410
bradshaw@mcn.org

Re: Comments on Proposed Regulation: Requirement for Pharmacies that Compound Medications

I would like to take the opportunity to comment on the proposed regulations entitled Requirements for Pharmacies that Compound Medications. I am a pharmacist practicing in a small rural hospital. I have been a pharmacist for 35 years and I have practiced in both large and small hospitals and in retail settings. I am drawing on my experience as a pharmacist in these practice settings as well as my examination of the requirements of USP 797 to make the following comments and suggestions.

The stated purposes for the proposed regulations are to define certain terms when used in referring to compounding, and to establish parameters for general compounding including the requirement for a quality assurance program. The regulations as proposed attempt to set forth a single set of regulations that cover both general compounding and sterile compounding for use in a variety of settings. These products may be self administered by a patient, administered by an independent practitioner, or administered by personnel in an institution or under the control of an institution where the compounding pharmacy is located. Pharmacy practice has become so complex that these examples represent only a few of the possible sites where we provide pharmaceuticals. I question the feasibility of having one set of regulations to govern both general compounding and sterile preparations compounding. It is also not feasible to attempt to cover all types of compounding without making specific regulations that would account for the specific needs that one would encounter in a given practice site. The attempt to cover all practice sites with a single set of regulations, without recognizing the inherent differences in the services provided, or the populations served, will result in a set of regulations that is incomplete, ambiguous and unduly burdensome.

The highest priority of the Board of Pharmacy as stated at Section 4001.1, Article 1, Chapter 9 Div. 2 of the Business and Professions Code, is the protection of the public. This can be achieved by providing pharmacy practitioners with a clear, unambiguous statement of the regulations.

In order to comply with the regulations, practitioners must have notice of the requirements. The proposed regulations do not give practitioners notice of the requirements. It is stated in the Factual Basis in the Initial Statement of Reasons for the proposed regulations that: "An inspector conducting an inspection is frequently asked questions regarding aspects of the inspection as well as clarifications and requirements of pharmacy law." Obviously, there is confusion about the various provisions of the existing pharmacy law and regulations. The new regulations do not clarify any of the ambiguities. It is my understanding that the inspectors have the authority to inspect facilities, not to interpret the law (See 4008, Business and Professions Code, Art. 1,Ch. 9, Div. 2). A clear statement of the regulations would give for proper notice, simplify the self-assessment process and provide uniformity in the inspection process.

It is my understanding that all sterile compounding is subject to the provisions of USP 797. Is it the intent of the Board to exempt California pharmacies compounding sterile preparations from the provisions of USP 797 that differ from the proposed regulations? If not, would it serve the Board's purpose to adopt the provisions of USP 797 as the rules, which would govern sterile compounding in California? Although USP 797 is very detailed, it has been thoroughly vetted by sterile compounding experts in the pharmaceutical community. Adoption of USP 797 would serve the purpose of protecting the public, and providing a clear unambiguous statement of the law that would give practitioners notice of the expectations of the law. It would also provide a reasonable

alternative to the proposed regulations as written. Since pharmacies compounding sterile preparations are subject to USP 797, it would not result in an additional financial impact. The impact on patient care must be weighed against business impact. The regulations as proposed would have a significant impact on patient care in hospitals:

The underlying data referred to in the Initial Statement of Reasons was reported in workgroup meetings, the last of which occurred in January 2005. A significant amount of discussion has taken place in the pharmaceutical community about compounded sterile preparations since that last meeting. The current USP 797 regulations are a result of that discussion.
Below, I have detailed specific sections of the proposed regulations that I believe are problematic.

Compounding Definitions
Many terms used throughout the body of the regulations have definitions that relate specifically to compounding. These terms should be defined. For example, the terms designated area, critical area and controlled area are all used when referring to sterile compounding.

Compounding Limitations and Requirements Sec. 1732.2
(a) The requirement that the prescriber approve use of a compounded drug either orally or in writing. Does this apply to chart orders? It is understood that most parenteral medications are compounded sterile products.

(h) Determining a beyond use date might also be determined by the nature of the compound. Evidence stronger than professional judgement of the pharmacist should be required. A requirement that the compounding provisions of USP 795 should apply could be added. The expiration or beyond use dating for compounded sterile preparations depends on both stability and sterility concerns. This should be stated.

(i) The pharmacist performing or supervising compounding, may not be the same pharmacist responsible for delivery of a compounded drug product. These activities may be performed by different individuals.

Records of Compounded Drug Products 1735.3
(a) Requiring the maintenance of these records for compounded sterile products administered in the hospital inpatient or outpatient setting would be unduly burdensome. These products are used if not immediately, then in a very short period of time there after. Except for batch prepared items, the detailed records this section would require offer little value.

(b) Would this require pharmacies compounding sterile products to maintain records of the acquisition of all sterile medications that are used to prepare sterile products, including IV solutions, and any medication that might be added to an IV solution? Would a hospital pharmacy performing minimal general compounding for an inpatient be required to keep records of items that might not have been purchased with the intent to use those items for compounding?

Labeling of Compounded Drug Products 1735.4
This section refers to Sec. 4076. Section 4076 (B) states that the paragraph applies to outpatient pharmacies only. Does Section 1735.4 refer to outpatient dispensing? Labeling requirements for sterile compounded preparations for administration in a hospital should have certain exemptions.

Training of Compounding Staff 1735.7
This section does not provide any guidelines about what is considered minimum skills, training or competency or competency assessment. As such, the determination of the sufficiency of the training or competency assessment would be left entirely to the inspector.

Article 7 Sterile Injectable Compounding

As stated before, I believe that adoption of USP 797 would provide the regulation of sterile compounding in California that the Board is attempting to achieve.

Compounding Area

The definition of a compounding aseptic barrier isolator should be added to Sec. 1751 concerning the compounding area.

USP 797 now requires certification of the ISO 5 compounding workstation twice a year in addition to other specified occasions. The proposed regulations require an annual certification with no requirement for recertification if the equipment is removed from service for repair or relocated.

Sterile Injectable Labeling Requirements 1751.2

(d)In addition to agents used in chemotherapy, NIOSH and OSHA have designated a group of agents as hazardous drugs. These agents are subject to special handling guidelines. The pharmacy regulations do not address hazardous drugs. Not all hazardous agents are used as chemotherapy. They can be used for a variety of other conditions. Proper handling, labeling, and disposal are important both for sterile compounding and general compounding. The regulations should address this topic.

Sterile Injectable Policies and Procedures 1751.3

Most of the requirements of (d) should apply to all sterile injectable compounding, not just to sterile compounding from one or more non-sterile ingredients.

Facility and Equipment Standards for Sterile Injectable Compounding 1751.4

The proper attire required in (b) should be specified.

(d) The weekly cleaning schedule specified conflicts with USP 797 in the pharmacies compounding only low and medium risk preparations are only required to clean monthly.

(e) The use of a compounding aseptic isolator for preparing parenteral cytotoxic agents should be allowed.

Sterile Injectable Compounding Attire 1751.5

This section specifies attire for personnel preparing cytotoxic and compounding from non-sterile ingredients. This section should be rewritten to cover all sterile compounding except for immediate use preparations.

The regulations do not adequately address the issue of protecting either compounding personnel or the public from unintended exposure to hazardous agents including chemotherapy. This should be included in the new regulations.

(5) The gloves used for sterile compounding should be more than gloves made from low shedding material. If not sterile gloves, then at least latex or nitrile gloves should be specified. Gloves that are ASTM rated for chemotherapy should be specified for personnel preparing cytotoxic agents.

Training of Sterile Injectable Compounding Staff

The requirements listed in (e) (1) A-H should be required of all personnel compounding sterile preparations.

These regulations will have a significant impact on the practice of pharmacy, especially in hospitals. This could be the opportunity for the Board to clarify some of the confusion with the existing regulations. This is the time to answer the questions and concerns of pharmacy practitioners. The vagueness and ambiguity of the regulations do not provide proper guidance to pharmacy practitioners.

I have only addressed some of the issues I find with the proposed regulations. I would be happy to discuss any of these with you.

Thankyou,

Margaret C. Bradshaw

October 2nd, 2008

Karen Cates
California Board of Pharmacy
1625 N. Market Blvd N219
Sacramento, California 95834
Karen_cates@dca.ca.gov

Re: Proposed Requirements for Pharmacies that Compound Medications

Dear Ms. Cates:

As an ED clinical pharmacist, I have concerns regarding sections of the proposed compounding regulations that pertain to new labeling and pharmacy record requirements with regard to certain compounded IV medications that would inevitably delay treatment to the direct of patient care.

It is common practice for a pharmacy in an acute care facility to prepare emergency compounded medications for the treatment of heart attack, stroke, and other life-threatening situations. Such patients require ***one-time and immediate-use (STAT) medications***, such as alteplase, epinephrine, or diltiazem for treatment. Added documentation requirements for both the label and pharmacy log will delay the preparation and delivery of these one-time and immediate-use medications; therefore, placing the patient at risk without any additional benefit to patient safety and care.

I do not see the advantage in delaying treatment for patients with critical conditions to record the pharmacy reference number or lot number on the label of each dispensed IV and the additional information in the pharmacy log when such labeling and recordkeeping requirements are primarily intended to be used in the event of a medication recall. I believe that such information would be obsolete in situations where patients are in need of one-time and immediate-use compounded products as any future recall of these products would be moot as the IV would be already administered to the patient.

As the proposed regulations stand now, every STAT compounded medication with life-saving potential prepared by a pharmacist during cardiac resuscitation, in the emergency department, in the operating rooms, or in other critical care areas would be delayed a few minutes longer to assure logging, assignment, and labeling of the IV bag with a pharmacy lot number.

Exempting immediate-use and one-time sterile products from some regulations has been done before. The recently updated United States Pharmacopeial Convention (USP) Chapter 797 has a special section related to *Immediate-Use Compounded Sterile Products* as the immediate-use provision is intended only for those situations where there is a need

for emergency or immediate patient administration of a compounded product.

As it relates to the preparation of one-time and immediate-use injectable products in acute care facilities, ***I request all proposed additional pharmacy record requirements be EXEMPTED from the pharmacy records. I also request an exemption of having to record the pharmacy reference number or lot number on the label for one-time and immediate-use IV medications.*** I believe that an exemption from additional record keeping requirements would be best to ensure that patients in acute care facilities with one-time and immediate-use needs are treated in a safe and appropriate timeframe.

These exemptions in STAT situations will certainly benefit and prolong patients' lives as they receive compounded medications urgently. I hope the following suggestions will help to meet our shared goal of better and safer patient care, and appreciate the board's willingness to consider our requests.

If you have any questions, please do not hesitate to contact me at (650) 724-2467.

Respectfully,

Carolyn Nguyen, Pharm. D.
ED Clinical Pharmacist, Stanford and Clinics Hospital, Stanford, CA
Phone: 650-724-2467
Fax: 650-725-5028

City and County of San Francisco
Department of Public Health
COMMUNITY BEHAVIORAL HEALTH SERVICES

Mayor Gavin Newsom

Pharmacy Services
1380 Howard Street, Rm 130
San Francisco, CA 94103
Phone: (415) 255-3659
FAX: (415) 252-3036

October 3, 2008

California State Board of Pharmacy
Attn: Karen Cates
1625 N. Market Blvd, N219
Sacramento, CA 95834

RE: Proposed New Compounding Regulations

Dear Ms. Karen Cates:

As a licensed working California pharmacist, with over 28 years experience in IV medication compounding, I've implemented compliance to USP <797> in multiple pharmacy practice sites for performance improvement and as a quality management function.

The proposed regulations require a "pharmacy reference number or lot number with each dispensed IV". I have strong concerns with this new requirement.
I understand the underlying reason for this new requirement is for the pharmacy to be able to trace back each unit of IV medication to its specific compounding information.
I recommend the regulations state that a pharmacy will be able to trace-back the pedigree (the compounding information) for an IV admixed product rather than prescriptively specifying the method of the trace-back.
For many pharmacies, information currently on the label would allow for this trace-back. The information includes prescription numbers, patient name, date and time of admixing. Adding the pharmacy reference number or lot number would be redundant information for identifying the pedigree of a compounded product.
Adding this new requirement would require significant amounts of extra work and time. Our pharmacy labor and expense resources are limited and should be used for what is best to ensure quality of services to our patients, not be put redundant extra information on the labels of our dispensed products.
From medication safety standpoint, information on the label should be limited to only what is required for safe dispensing and administering the medication. Adding the lot number or pharmacy reference numbers adds more information to an already busy IV label, increasing the risk of confusion by patients or nurses in administering the

medication. An overload of information on the medication label discourages patients and nurses to verify critical basic information such as patient name, medication name expiration dating and proper storage information.

The proposed regulations 1735.2(a) would require prescribers to specify "the prescriber has approved use of a compounded drug product either orally or in writing". Will this be required for all prescriptions to be compounded including the hospital setting? Would it include prescriptions which can only be dispensed compounded such as an individualized TPN? My understanding of this proposed regulation is that prescribers are required to specify compounding on the prescription, and if not specified, the pharmacist would be required to call to obtain a verbal order. Based on my experience, it would be near impossible for prescribers to be aware and then remember the need to add the compounding specifics to the prescription. **I am concerned that this requirement does not add to patient safety but rather would require additional pharmacist time and resources, and cause delays in filling the prescription. I urge the Board to remove this proposed requirement.**

Please feel free to contact me for further discussion.

Sincerely,

Gloria Lee Wilder, Pharm.D
CBHS Pharmacy Director
San Francisco Department of Public Health
1380 Howard Street, #130, San Francisco, CA 94103
Gloria.wilder@sfdph.org
415-255-3703

Maria D. Serpa, Pharm.D.
6744 Paseo Del Sol
Elk Grove, California 95758
serpam@sutterhealth.org

October 3, 2008

Board of Pharmacy
Attn: Karen Cates (Proposed Compounding Regulation)
1625 N. Market Blvd. N219
Sacramento, CA 95834
karen_cates@dca.ca.gov

Re: Proposed Regulations - Article 4.5 General Compounding

Dear Ms Cates:
I am very concerned with the sweeping changes proposed to the compounding and documentation of ***sterile injectable*** products. As I understand it, the California Board of Pharmacy was originally tasked to strengthening compounding practice and safety for ***"traditional"*** compounding. This area of pharmacy practice lacks specific regulation to adequately protect patients. My concern is that now ***sterile injectable*** compounding is lumped together with the ***"traditional"*** form of compounding and this added a layer of regulation is not necessary at this time. Current regulations regarding ***sterile injectable*** compounding are very specific and detailed from both the United States Pharmacopeia (USP) Convention guidelines at the federal level and current state BOP regulations.

I suggest ***sterile injectable*** and ***non-sterile*** compounding be maintained in separate regulations. Current California regulations, Article 7 Section 1751 (Sterile Injectable Compounding) and Business & Professions Code Section 4127 (Injectable Sterile Drug Products) cover the issues related to ***sterile injectable*** compounding. These current regulations contain the required elements (e.g., facility and equipment standards, policies and procedures, labeling and recordkeeping requirements, training and quality assurance processes) to assure patient safety. In addition, the Board requires additional licensure or accreditation of pharmacies to perform the functions of ***sterile injectable*** compounding. Changes or additional regulations to these sections are NOT needed.

The requirements for the safe preparation of ***sterile injectable*** and ***"traditional" non-sterile*** products are distinctly different. The United States Pharmacopeia (USP) regulates these processes separately in 2 distinct chapters. USP 797 deals with Pharmaceutical Compounding – Sterile Preparations and USP 795 deals with Pharmaceutical Compounding – Nonsterile Preparations.

I am additionally concerned patient care may be jeopardized by the additional documentation requirements suggested for ***sterile injectable*** compounding if lumped together with ***"traditional" non-sterile*** compounding. It is common practice for a pharmacy in an acute care facility to prepare emergency medications for the treatment of heart attack, stroke and other life-threatening situations. Currently these *STAT, one-time, immediate- use* medications are prepared in the pharmacy and labeled with adequate information to assure patient safety and recall should a medication be recalled in the next few hours during administration. Additional record keeping or generation of a pharmacy specific lot number for each injectable product compounded does not serve the patient. It only delays STAT medication preparation and delivery and places an

additional burden on the pharmacy. If changes are planned for sterile injectable compounding, exempting *immediate-use* sterile products from some of the documentation requirements is prudent to assure patient safety. This has been done before. The recently updated USP Chapter 797 has a special section related to Immediate-Use Compounded Sterile Products.

Thank you for considering these issues. I ask that the Board address the patient safety needs of ***"traditional" non-sterile*** compounding and move forward on those regulations. This is urgently needed. There is no need to change the current status and regulations for ***sterile injectable*** compounding.

Respectfully,

Maria D. Serpa, PharmD

October 3, 2008

Virginia Herold
Executive Officer
California Board of Pharmacy
1625 N. Market Blvd N219
Sacramento, California 95834

SUBJECT: PROPOSED REQUIREMENTS FOR PHARMACIES THAT COMPOUND MEDICATIONS

Dear Ms. Herold:

This letter is to support the California Society of Health-System Pharmacists position regarding labeling and record keeping exemptions for one-time and immediate-use medications.

I believe that the USP Chapter 797 section on Immediate Use Compounded Sterile Products allows exemptions for emergency or immediate use of a compounded product—in particular in an acute care setting.

As a long time hospital pharmacist, I urge the Board of Pharmacy to grant this exemption, which will be in the best interest of patient safety and quality of care.

Sincerely,

Larry W. Schallock
PO Box 428
San Luis Rey, CA 92068

RPh 25825

RECEIVED BY CALIF
BOARD OF PHARMACY
2008 OCT -3 PM 4:20

Board of Pharmacy
Attention: Karen Cates (Proposed compounding regulations)
1625 Market Blvd., N219
Sacramento, Ca 95834

September 27, 2008

Dear Board of Pharmacy,

I am writing as a pharmacist with a 27-year history in the practice of Hospital Pharmacy. I am writing to pass along my strong opposition to your proposed compounding regulations, which, if not edited or clarified would have a significant negative impact on established pharmacy practice.

The standard of practice in hospital pharmacy for preparing IV admixtures is one that has been refined and continually updated by the pharmacy profession. Most recently, the extensive changes of the USP 797 requirements have further defined and altered the hospital pharmacy practice of preparing IV admixtures. The major problem with the proposed regulations by the Board of Pharmacy is the definition and distinction of what is considered a compounded item. It is my strong belief, and one I believe is shared by anyone in the hospital pharmacy profession, that IV admixture preparation practice should be not bundled in with compounded prescriptions (topical, oral, injectables compounded from non-sterile product or intended for sale or distribution to a patient or provider).

The most significant problem is with regulations 1735.3 and 1751.1 – the proposed recordkeeping regulations and they should NOT be passed. If the regulations are passed as proposed, and the intent is to apply it to all IV admixtures prepared in a hospital pharmacy environment, it would be a recordkeeping nightmare. The majority of IV admixtures prepared in the hospital setting fall within the low to medium risk category as well defined and described by USP 797. If for every IV admixture prepared the Board would expect to see LOT #, manufacturer, equipment used, personnel identity, pharmacist identity, pharmacy lot number, expiration dating, quantity, etc as described in 1735.3, the treatment of acutely ill patients would be at risk. Even in a small, rural critical access hospital we often mix over 100 IV admixtures in a day. In a larger institution, this number would be 10-20 times higher and the recordkeeping requirements, which the regulations imply, would be overwhelming and create an enormous burden on pharmacy professionals. Furthermore, I believe this extensive recordkeeping would not significantly improve medication or patient safety.

I strongly recommend that you **do not pass** the proposed regulations as they are currently written and you evaluate the intent of the regulations for all aspects of professional pharmacy practice. Specifically, please consider the recommendations and consultation of pharmacy professionals within hospital pharmacy practice and how the "sterile compound" regulations pertain to the practice of IV admixture services.

In addition to the above considerations, please reconsider the language of 1751.5, 1751.6 and 1751.7. It would seem prudent to follow the practice guidelines for USP 797 in the areas such as training, cleaning, garbing, and quality assurance as these standards have been reviewed by a group of nationally recognized individuals.

Thank you for your consideration of this letter.

Sincerely,

Lois F. Leister, RPh, M.S., M.B.A.
Practicing hospital pharmacist, Member of CSHP
29930 Sherwood Road
Fort Bragg, CA 95437
Email lfander@mcn.org

"Azama-Kihara, Karen - MSJ" <Karen.Azama-Kihara@chw.edu>

10/05/2008 09:22 PM

To <karen_cates@dca.ca.gov>

cc

bcc

Subject Against Proposed IV Compounding Regulations

Dear Ms. Cates,

I am writing to let you know I am against the new proposed regulation to require pharmacists to record in a log each IV compounded. I feel there must be exemptions in life threatening and emergent situations. To require a delay in services to log a medication prepared during a cardiac arrest or other emergent situation could be detrimental to the patient. As a former ICU pharmacist who attended many code blues, this would have created unncessary stress, and would not have provided any added safety benefit to the dying patient.

I am requesting that all proposed additional pharmacy record keeping requirements for the preparation of one-time and immediate use IV products in the acute care hospital be exempted.

I am also requesting an exemption from having to record the pharmacy reference number or lot number on the label for one-time and immediate-use IV medications.

Thank you for taking my concerns for our profession and our patients' safety into consideration.

Karen Azama-Kihara, Pharm. D.
Pharmacy Supervisor
Mercy San Juan Medical Center

"Chan, Gary - MSJ"
<gary.chan001@chw.edu>
10/06/2008 12:33 AM

To <karen_cates@dca.ca.gov>
cc
bcc
Subject Proposed IV Compounding Regulations

October 6, 2008

Karen Cates
California Board of Pharmacy
1625 N. Market Blvd. N219
Sacramento, CA 95834
karen_cates@dca.ca.gov

Re: Proposed Requirements for Pharmacies that Compound Medications

Dear Ms. Cates,

I am writing to let you know that I am strongly opposed to the new proposed regulation to require pharmacists to record in a log each IV compounded. Being a clinical pharmacist working in the different units of a hospital, I am required to attend codes, rapid responses, and cardiac alerts. I do not see a benefit in the new regulation proposed. In fact, I see plenty of harm to the patient if this regulation were actually put in place. There are plenty of instances when these patients require "immediate" and "one time" STAT medications. The new proposed regulation would only hinder our ability to provide quick and safe care for these critical patients at their bedside. This would only create unnecessary stress, and would not provide any added safety benefit to the dying patient.

I am requesting that all proposed additional pharmacy record keeping requirements for the preparation of one-time and immediate use IV products in the acute care hospital be exempted. I am also requesting an exemption from having to record the pharmacy reference number or lot number on the label for one-time and immediate-use IV medications.

Thank for your time and consideration.

Gary W. Chan
Clinical Pharmacist
Mercy San Juan Medical Center

Sutter Lakeside Hospital

To: California Board of Pharmacy
Attention: Karen Cates (Proposed Compounding Regulation)
1625 N. Market Blvd. N219
Sacramento, CA 95834
Fax: (916) 574-8618

I would like to register my professional opinion regarding this proposed change. I am a 1972 graduate of U.C. San Francisco, also completing a clinical residency from U.S.C. School of Pharmacy in 1973. I have been a faculty member of the University of Michigan, U.S.C. and Western University Schools of Pharmacy; I have published articles pertaining to antibiotic therapy, pharmacokinetics, and pharmacy practice. For the last 30 years, my practice has been in acute care hospitals, primarily as a manager & clinical pharmacy practice promoter. During that time I have been either director or assistant director of 13 acute care facilities ranging from 25 beds to 530 beds.

I have seen many positive changes in our practice, witnessed the growth of our profession from a dispenser of medications to a true member of the health care team. I have also seen the barrage of regulations that have obvious good intentions come from varius regulatory agencies including the Board of Pharmacy, but do not seem to "connect" in practice. Often the issues are related to inability to decipher the specific intent of the regulations – usually because they are written in legal language, and not in the language of the public nor healthcare. This confusion is reflected by various "interpretations" by individual inspectors of the same regulation. This regulation change is clear!

With respect to the proposed changes, my primary focus is on the requirement for one-time or administered immediately "compounded" preparations. I ask the question, "What is the purpose?" In the event of a recall, even that very day, the medication has been administered & can not be returned to the Pharmacy! To require additional labeling & maintenance of a log seems to be illogical and serves absolutely no useful purpose for the public with respect to safety, nor to the Board of Pharmacy.

I am aware that various official organizations, including CSHP and others, have made similar requests. As a practicing pharmacist, I ask that you strongly reconsider this aspect of the proposed regulatory change and grant an exemption for medications "compounded" for immediate or emergency use.

Thank you for your consideration,
Sincerely,

Ben J. Devine, PharmD

Ben J Devine, PharmD (RPh 27902)
Director of Pharmacy
Sutter Lakeside Hospital
5176 Hill Road East
Lakeport, CA 95453

American Society of
Health-System Pharmacists®
7272 Wisconsin Avenue
Bethesda, Maryland 20814
301-657-3000
Fax: 301-664-8892
www.ashp.org

October 6, 2008

Ms. Virginia Herold
Executive Officer
California Board of Pharmacy
1625 N. Market Blvd., N219
Sacramento, CA 95834

RE: Proposed Regulatory Changes Regarding Compounding

Dear Ms. Herold:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit the following comments regarding the proposed regulatory changes in Article 4.5, Compounding, of the California Code of Regulations. For more than 60 years, ASHP has helped pharmacists who practice in hospitals and health systems improve medication use and enhance patient safety. The Society's 35,000 members include pharmacists and pharmacy technicians who practice in inpatient, outpatient, home-care, and long-term-care settings, as well as pharmacy students.

Compounding medications is a significant facet of the practice of pharmacy and we applaud the Board of Pharmacy's desire to ensure that patient safety is protected. ASHP also recognizes the importance of developing regulatory language that provides necessary parameters while avoiding potentially significant barriers to providing patient care. As such, having reviewed the proposed regulatory changes, ASHP does have some concerns regarding the labeling and documentation modifications within the proposed regulations.

The proposed regulatory change to labeling is of concern to ASHP. In the United State Pharmacopeial's revised *USP <797>, Guidebook to Pharmaceutical Compounding - Sterile Preparations*, it states that "unless immediately and completely administered...the [compounded sterile preparation (CSP)] shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour beyond-use date (BUD) and time."[1] This revision allows for less stringent labeling, as long as the compounded product meets all of the stated criteria.

Current ASHP practice guidelines recognize that states have the right to require specific labeling. Enclosed is a copy of the guideline's labeling requirements for sterile

[1] *USP <797> Pharmaceutical Compounding – Sterile Preparations*. Revised 2008. Pg. 13.

preparations. These labeling requirements are more detailed that the current USP revision; however, these guidelines specifically exclude the compounding of sterile preparations for emergency treatments from its scope, a vital distinction that we believe is necessary:

> "These ASHP guidelines *do not* apply to the manufacture of sterile pharmaceuticals as defined in state and federal laws and regulations, *nor* do they apply to the preparation of medications by pharmacists, nurses, or physicians in emergency situations for *immediate* administration to patients (e.g., cardiopulmonary resuscitation)...It is recognized that, in certain emergency situations, a pharmacist may be requested to compound products under conditions that do not meet these guidelines. In such situations, it is incumbent upon the pharmacist to employ professional judgment in weighing the potential patient risks and benefits associated with the compounding procedure in question."[2]

ASHP believes that the compounding of sterile preparations in emergency situations should be governed by the professional judgment of pharmacists and the policies of the institutions they practice in, as those situations demand that health care professionals have the utmost flexibility to decide what is best for the patient. We would, therefore, strongly encourage the Board to reconsider the current proposed language. While labeling requirements during normal events are beneficial to both the pharmacy and the patient, such strict requirements during emergency situations could negatively impact patient care and introduce delays in medication delivery. As currently proposed, the labeling requirement could in fact create the opposite effect than intended – delays in patient care that places patient health and safety in jeopardy.

In terms of the proposed changes to documentation, there may be some confusion as to whether the documentation requirement applies to every product that is prepared, including those for an individual patient, or if the new requirement will apply solely to those products that are prepared in batch for a yet-to-be determined patient. As pharmacies typically do not record such detailed information for patient-specific items, such a proposed regulation could create an extraordinary burden for pharmacies. Further, not only could this new requirement exist for emergency drugs, it could impact all products prepared for routine care. This added documentation requirement has the potential to delay the preparation and delivery of one-time and immediate-use medications. We would urge the Board to consider the potential implications of such a regulatory change.

We appreciate the opportunity to provide these comments and would be happy to work with you as you continue to develop appropriate guidelines and requirements that affect

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[2] American Society of Health-System Pharmacists. ASHP Guidelines on Quality Assurance for Pharmacy-Prepared Sterile Products. Am J Health-Syst Pharm. 2000; 57:1150–69. pg. 54. (available at: http://www.ashp.org/DocLibrary/BestPractices/QualityAssurance.aspx)

the pharmacy profession. If you have any questions or comments, please do not hesitate to contact me at 301-664-8687 or gtrujillo@ashp.org.

Sincerely,

Geralyn Trujillo

Geralyn Trujillo, MPP
Director, State Government Affairs

cc: Philip Swanger, California Society of Health-System Pharmacists

Enclosure

ASHP Guidelines on Quality Assurance for Pharmacy-Prepared Sterile Products

RL 1.9: Labeling.
Sterile products should be labeled with at least the following information:

1. For patient-specific products: the patient' name and any other appropriate patient identification (e.g., location, identification number); for batch-prepared products: control or lot number,
2. All solution and ingredient names, amounts, strengths, and concentrations (when applicable),
3. Expiration date and time, when applicable,
4. Prescribed administration regimen, when appropriate (including rate and route of administration),
5. Appropriate auxiliary labeling (including precautions),
6. Storage requirements,
7. Identification (e.g., initials) of the responsible pharmacist (and technician),
8. Device-specific instructions (when appropriate), and
9. Any additional information, in accordance with state or federal requirements; for example, a prescription number for products dispensed to ambulatory care, long-term-care, and home care patients.

The label should be legible and affixed to the final container in a manner enabling it to be read while the sterile product is being administered (when possible). Written policies and procedures should address proper placement of labels on containers.

PETNET Solutions

VIA EMAIL

California Board of Pharmacy
Attention: Karen Cates and Virginia Herold (Proposed Compounding Regulation)
1625 N. Market Blvd., N219
Sacramento, CA 95834
virginia_herold@dca.ca.gov
karen_cates@dca.ca.gov

October 6, 2008

RE: Title 16, Division 17 Proposed Changes

PETNET Solutions, Inc., a Siemens Company (DBA PETNET Pharmaceutical), operates specialty compounding nuclear pharmacies preparing solely radiopharmaceuticals for use in Positron Emission Tomography (PET) nuclear medicine diagnostic imaging studies. PETNET operates forty-five PET Nuclear Pharmacies in the US, with four locations in the state of California operating under both retail and sterile compounding pharmacy licenses.

The State of California does not provide unique regulations or significant special requirements for the operation and licensure of Nuclear Pharmacies (Radiopharmacies) in its statutes. Recently, the USP, in their revised Chapter <797>, *Pharmaceutical Compounding, Sterile Preparations*, recognized the significant differences in the nature of the products compounded for use in nuclear medicine and the nature by which such products are compounded. USP Chapter <797> further differentiates the relevant differences in radiopharmaceuticals used in PET from traditional radiopharmaceuticals by deferring most of the requirements in USP <797> to USP Chapter <823>, *Radiopharmaceuticals for Positron Emission Tomography-Compounding*.

The Food and Drug Administration Modernization Act of 1997 (public Law 105-115, FDAMA '97), Section 121, sets the legal requirements for the compounding of PET radiopharmaceuticals in the US. Producers of PET radiopharmaceuticals are legally bound by this law, and FDA currently inspects PET Nuclear Pharmacies for compliance to this law regardless of whether the PET compounding facility if registered as a drug establishment with FDA or not. Ultimately, as stipulated under FDAMA '97, FDA is required to regulate the compounding (production) of such drugs under a specific PET GMP regulation once the regulation is formally adapted into the Code of Federal Regulations in the future. Two years after FDA codifies the PET cGMP regulations in the CFR, FDA will require PET drug producers to register their drug establishments with FDA and to submit Human Drug Applications to the FDA.

Some unique differences between conventional drugs, conventional radiopharmaceuticals, and PET radiopharmaceuticals are:

- They cannot be purchased from a traditional commercial source.
- No radionuclide generators are employed

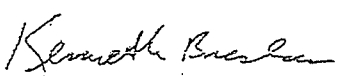
- No pre-manufactured radiopharmaceutical kits are employed.
- The physical half-life of the radionuclides used in PET radiopharmaceuticals ranges from 2 minutes to 110 minutes.
- The radioactive emissions are of very high energy compared with traditional radiopharmaceuticals thus requiring much more rigorous radiation shielding and remote physical handling.
- The radio-labeling of the ligand takes place in situ via an automated chemical synthesis unit utilizing a radionuclide extracted from a cyclotron target after the bombardment of a stable starting isotope. The synthesis module cannot be placed in an aseptic environment.
- Some non-sterile reagents and precursors are used.
- The finial products are aseptically processed and sterilized by filtration into a sterile product vial.
- The quality control testing of each batch produced prior to release for patient use is extensive.
- The delivery of the finished radiopharmaceutical is highly time-critical because of the very short physical half-life of the isotopes employed.
- The expiration date is no greater than 12 hours after compounding
- Sterility testing is started when compounded, but the product must be used prior to the completion of the sterility test.

PETNET urges the California Board of Pharmacy to carefully consider the potential impact of their proposed revised regulations on Nuclear Pharmacies and PET Nuclear Pharmacies in light of the special nature of these drugs. PETNET further encourages the Board to avoid regulations that conflict with the requirements of those currently in place in the current revision of the USP Chapters <797> and <823> as applied to radiopharmaceuticals in general, and specifically to compounded PET radiopharmaceutical products.

PETNET suggests that it may be prudent for the Board to exempt the application of any revised sterile compounding regulations to PET drug compounding and stipulate the requirement to comply with the relevant USP chapters until such time the Board proposes and adopts its own regulations pertinent and applicable to radiopharmaceutical and PET radiopharmaceutical compounding

PETNET anticipates having a representative attend the October public hearings on this topic to offer expert input into the Boards rule making activities.

Sincerely,



Kenneth Breslow, MS, R.Ph., FAPhA

CC:
Michael Nazerias
Dwayne Mar
Josh Nutting
Jerry Kuhs

October 6, 2008

Board of Pharmacy
Attn: Karen Cates
1625 N. Market Blvd. N219
Sacramento, CA 95834
Fax: (916) 574-8618
karen_cates@dca.ca.gov

Re: Proposed Compounding Regulation

I am writing in regards to the proposed compounding regulations (starting with Section 1716), specifically the record keeping and labeling requirements.

I am very concerned that these requirements in acute care hospitals with large number of compounded IV medications would be very burdensome. The majority of these compounded IV medications are used within 24 hours, sometimes immediately, after being compounded.

In the acute care setting these compounded IV medications are used by very few patients, sometimes a single patient and for a very limited amount of time. Thus the typical batch compounding issues encountered in an chronic care setting (e.g., Home health or ambulatory care) do not apply.

I would respectfully request that the Board consider an exemption from the record keeping and labeling requirements in acute care facilities for IV compounded IV medications for immediate use.

Sincerely,

Robert Batman, Pharm.D.

Dear State Board of Pharmacy,

This letter is being written on behalf of the 3rd Year Community Pharmacy Management Elective at the University of Southern California School of Pharmacy. As a class project, out students were instructed to conduct a survey of community pharmacies to ascertain whether or not the proposed compounding regulation changes would affect community pharmacies. In contacting 12 random community pharmacies we were surprised that only 2 of the pharmacies were aware of the proposed regulation changes and the balance of pharmacies were unaware of the proposals. The conclusions that our class arrived at from our interview with these pharmacists are the following:

1) The regulation seems to hinder access in some unique situations. Particularly, community pharmacies that prepare compounded medications on a limited basis may completely halt their compounding activities due to the cost factors of having to meet the regulatory standards (end product testing, possible purchase of software, etc.). In our opinion, this may limit some pharmacies from changing dosing forms on a patient need basis. It will also make access to this service more limited for the general population. Furthermore, pharmacies that may stop preparing compounded medications have long standing relationships with certain patients that have been receiving their compounded prescriptions from the same pharmacy that prepares their non-compounded prescriptions. These regulations may cause these patients to switch pharmacies, and result in loss of revenue for the pharmacy and the loss of a long standing relationship between a pharmacist and a patient.

2) The regulations refer to end-product testing and quality assurance without clearly defining it. Pharmacists that were spoken to seemed to all agree that the proposed regulations do not clearly define issues regarding end-product testing, such as frequency of end-product testing, requirements for record keeping, and which products need to be tested.

3) The regulation did not make any distinction between the complexity of compounding and the amount of regulation needed. For example mixing two different products to create a cream or changing a tablet to a liquid dosing form for short term administration should not require as much oversight as complex compounding formula. We feel that this area needs to be further explored.

In conclusion we all agreed that regulations were needed in this area, but there needed to be some criteria for the amount of regulation needed vs. the difficulty of preparing a particular compounded medication. We want to thank you for the opportunity to present our opinion and those of community pharmacists in the Southern California community we interviewed.

Raffi Svadjian Pharm.D, MBA
Co-course Coordinator

Michael J. Rudolph Pharm.D
Co-course Coordinator

Proposed Language Citation # & Page #	Concern	Recommended Change Wording in plain text represent proposed BOP language Wording in *italics* is proposed language by KP. Text marked by ~~crossouts~~ designate proposed deletions.	Priority
1735.2(c)(1) Page 3 of 16	The proposed language appears to limit compounding for a physicians office to a 72 hour supply. For products administered in the office this is an unreasonably short time. According to USP <797>, risk level 1 CSPs and risk level 2 CSPs may be assigned a beyond use date of up to 14 days and nine (9) days, respectively, when stored under refrigeration. This would be a more reasonable length of time.	is sufficient for administration or application to patients in the prescriber's office, or for dispensing of not more than a 72 hour *supply* to the prescriber's patients, as estimated by the prescriber; and…	high
1735.2(d) Page 3 of 16 1735.3(a) Page 4 of 16	The scope of the proposed language appears to include most compounded sterile preparations (CSPs) in inpatient pharmacies. Inpatient pharmacies typically prepare CSPs to meet the acute needs of patients. Requiring a master formula for small quantities of patient-specific CSPs would cause significant delays in therapy. In addition, inpatient pharmacies already have policies and procedures which require the amounts of additives to be calculated and displayed for a pharmacist check. This proposed language would be appropriate only when batches of compounded products are prepared which are intended for use in multiple patients.	(d) *For compounded drug products that are being prepared for use in multiple patients, these products* shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:	high
1735.2 (f) Page 4 of 16	While this language is appropriate in the case of a pharmacist who is compounding a sterile preparation (CSP) for direct dispensing to a patient or their agent, it is not appropriate if a pharmacist compounds a CSP that is transferred to another pharmacy pursuant to an evergreen agreement. In the latter scenario, the compounding pharmacist has no control over the CSP after it has left the pharmacy where the compounding occurred. If the CSP isn't stored properly (e.g. storing at room temp instead of	The pharmacist performing or supervising compounding is responsible for the integrity , potency, quality, and labeled strength of a compounded product until it is dispensed *to the patient (or their agent), to a physician's office, or until it is transferred or distributed to another pharmacy.*	high

Proposed Language Citation # & Page #	Concern	Recommended Change Wording in plain text represent proposed BOP language Wording in *italics* is proposed language by KP Text marked by ~~crossouts~~ designate proposed deletions.	Priority
	under refrigeration), the compounding pharmacist would have no knowledge of this; thus (s)he should not be the responsible party. Rather, the pharmacist in charge of the receiving pharmacy should be the responsible party.		
1735.8 (c) Page 7 of 16	This language appears to be directed towards compounding from non-FDA approved ingredients. It is inappropriate for compounding sterile products from sterile FDA approved ingredients. When preparing sterile products from FDA approved sterile ingredients, a quality assurance plan should only require written standards for visual checks of the final product.	*There should be a statement that exempts the preparation of products from FDA approved ingredients from subsection (c).*	High
1751.3(a)(2) Page 10 of 16	As proposed, this language requires that the labels of sterile injectable products display the recommended rate of administration. The recommended rate of administration on a product label can be unhelpful and incorrect. There are two common scenarios to support this point. 1. Due to dynamic patient clinical needs, physicians frequently order broad dosage ranges of vasoactive drugs, which result in equally broad ranges of administration rates. Example: a physician orders dopamine to be infused at a dose of 10 to 20 mcg/kg/min for a 70 Kg patient in order to maintain systolic blood pressure above a certain value. The pharmacy dispenses dopamine 800mg in D5W 250mL. According to the proposed language in this section, the product label would display an	(2) Labeling of the sterile injectable product based on the intended route of administration. ~~and recommended rate of administration.~~ *Facility policies shall state the circumstances whereby it is appropriate to display recommended rates of administration or duration of medication infusions.*	high

Proposed Language Citation # & Page #	Concern	Recommended Change Wording in plain text represent proposed BOP language Wording in *italics* is proposed language by KP Text marked by ~~crossouts~~ designate proposed deletions.	Priority
	administration rate of 13 to 26 mL/hour – a two-fold range which is not helpful to the nurse administering the drug. 2. Physicians often order frequent rate changes for other products, such as I.V. maintenance fluids and anticoagulants. If the pharmacy dispenses a product with a label displaying the initially ordered rate, and if the physician orders a rate change two hours later, the administration rate information in the product label becomes incorrect (and potentially misleading). In these cases, the initial administration rate on the product label would be considered incorrect the moment a physician orders a rate change. Nurses are instructed to use medication administration records or flow sheets to keep track of the most current administration rate for these types of products. On the other hand, there are some compounded products for which the ordered administration rate will not change, and the administration rate or infusion time is useful on product labels (eg. Cefazolin 1 gram in D5W 100 mL; infuse over 30 minutes). This information is commonly displayed on product labels because it improves the clarity and completeness. Inpatient pharmacies should have policies regarding the content of medication labels, including when it is appropriate to display the administration rate.		
1751.4 (d) Page 11 of 16	This language, describing the cleaning frequency of ceilings, walls, etc previously applied to sterile preparations compounded from non-sterile ingredients. The weekly cleaning frequency as described is excessive and unnecessary for sterile preparations compounded from sterile	Proposed change to language: Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected ~~weekly~~ *monthly* and after any	high

Proposed Language Citation # & Page #	Concern	Recommended Change Wording in plain text represent proposed BOP language Wording in *italics* is proposed language by KP Text marked by ~~crossouts~~ designate proposed deletions.	Priority
	ingredients, however. If the BOP intends for the title of this section to read, "Facility and Equipment Standards for Sterile Injectable Compounding", then this language must change.	unanticipated event that could increase the risk of contamination.	
1751.4(e) Page 11 of 16	This language appears to recognize laminar air flow hoods (presumably biological safety cabinets) as the appropriate equipment for preparation of parenteral cytotoxic agents. Barrier isolators are recognized by the American Society of Health-Systems Pharmacists and the USP as appropriate equipment as well. The use of barrier isolators should be stated in this subsection.	Pharmacies preparing parenteral cytotoxic agents shall be do so in accordance with Section 4-1106(b) of Title 24 of the California Administrative Code, requiring a laminar air flow hood *or barrier isolator*. The hood or isolator must be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications. Certification records must be retained for at least 3 years. Authority cited: Sections 4005 and 4127, Business and Professions	medium
1751.7 (d) Page 16 of 16	As proposed, this language appears to reintroduce end product sterility testing for CSPs made from sterile ingredients using aseptic transfers. This is of no value and must be deleted. If the BOP intended for subdivision (d) to apply to non-sterile to sterile compounding, it should be stated explicitly. If the BOP intended this language to apply to sterile to sterile compounding, existing 1751.7 (b) describes the appropriate process very well and should be retained.	Delete this proposed language: ~~Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures.~~ Insert this language excerpted from current 1751.7 (b): *Each individual involved in the preparation of sterile injectable products must successfully complete a validation process on technique before being allowed to prepare sterile Injectable products. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The*	high

Proposed Language Citation # & Page #	Concern	Recommended Change Wording in plain text represent proposed BOP language Wording in *italics* is proposed language by KP Text marked by ~~crossouts~~ designate proposed deletions.	Priority
		validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The same personnel, procedures, equipment, and materials are involved. Completed medium samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated. Personnel competency must be revalidated at least every twelve months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. Revalidation must be documented.	

Specific Language to Amend Title 16 CCR Section 1773 And Add Title 16 CCR Section 1773.5 Ethics Course

Amend Section 1773 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1773. Disciplinary Conditions of Probation of Pharmacist.

(a) Unless otherwise directed by the Board in its sole discretion, any pharmacist who is serving a period of probation shall comply with the following conditions:

(1) Obey all laws and regulations substantially related to the practice of Pharmacy;

(2) Report to the Board or its designee quarterly either in person or in writing as directed; the report shall include the name and address of the probationer's employer. If the final probation report is not made as directed, the period of probation shall be extended until such time as the final report is made;

(3) Submit to peer review if deemed necessary by the Board;

(4) Provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the Board;

(5) Inform all present and prospective employers of license restrictions and terms of probation. Probationers employed by placement agencies must inform all permittees in whose premises they work of license restrictions and terms of probation.

(6) Not supervise any registered interns nor perform any of the duties of a preceptor;

(7) The period of probation shall not run during such time that the probationer is engaged in the practice of pharmacy in a jurisdiction other than California.

(b) If ordered by the Board in an administrative action or agreed upon in the stipulated settlement of an administrative action, any registered pharmacist who is serving a period of probation shall comply with any or all of the following conditions;

(1) Take and pass all or any sections of the pharmacist licensure examination and/or attend continuing education courses in excess of the required number in specific areas of practice if directed by the Board;

(2) Provide evidence of medical or psychiatric care if the need for such care is indicated by the circumstances leading to the violation and is directed by the Board;

(3) Allow the Board to obtain samples of blood or urine (at the pharmacist's option) for analysis at the pharmacist's expense, if the need for such a procedure is indicated by the circumstances leading to the violation and is directed by the Board;

(4) If and as directed by the Board, practice only under the supervision of a pharmacist not on probation to the Board. The supervision directed may be continuous supervision, substantial supervision, partial supervision, or supervision by daily review as deemed necessary by the Board for supervision, partial supervision, or supervision by daily review as deemed necessary by the Board for the protection of the public health and safety.

(5) Complete an ethics course that meets the requirements of section 1773.5.

(c) When the circumstances of the case so require, the Board may impose conditions of probation in addition to those enumerated herein by the terms of its decision in an administrative case or by stipulation of the parties.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4300, Business and Professions Code.

Deletions to the regulatory text are indicated by double strike-through, thus: ~~deleted language~~. Additions to the regulatory text are indicated by a double underline, thus: added language.

Add Section 1773.5 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1773.5 Ethics Course Required as Condition of Probation.

When directed by the board, a pharmacist or intern pharmacist may be required to complete an ethics course that meets the requirements of this section as a condition of probation, license reinstatement or as abatement for a citation and fine. Board approval must be obtained prior to the commencement of an ethics course.

a. The board will consider for approval an ethics course that at minimum satisfies the following requirements:

(1) Duration. The course shall consist of a minimum of 22 hours, of which at least 14 are contact hours and at least 8 additional hours are credited for preparation, evaluation and assessment.

(2) Faculty. Every instructor shall either possess a valid unrestricted California professional license or otherwise be qualified, by virtue of prior training, education and experience, to teach an ethics or professionalism course at a university or teaching institution.

(3) Educational Objectives. There are clearly stated educational objectives that can be realistically accomplished within the framework of the course.

(4) Methods of Instruction. The course shall describe the teaching methods for each component of the program, e.g., lecture, seminar, role-playing, group discussion, video, etc.

(5) Content. The course shall contain all of the following components:

(A) A background assessment to familiarize the provider and instructors with the factors that led to the prospective candidate's referral to the class.

(B) A baseline assessment of knowledge to determine the participant's knowledge/awareness of ethical and legal issues related to the practice of ~~medicine~~ pharmacy in California, including but not limited to those legal and ethical issues related to the specific case(s) for which the participant has been referred to the program.

(C) An assessment of the participant's expectations of the program, recognition of need for change, and commitment to change.

(D) Didactic presentation of material related to those areas that were problems for the participants based upon the results of the background assessments and baseline assessments of knowledge.

(E) Experiential exercises that allow the participants to practice concepts and newly developed skills they have learned during the didactic section of the class.

(F) A longitudinal follow-up component that includes (1) a minimum of two contacts at spaced intervals (e.g., 6 months and 12 months) within one year after course completion or prior to completion of the participant's probationary period if probation is less than one year, to assess the participant's status; and (2) a status report submitted to the division within 10 calendar days after the last contact.

(6) Class Size. A class shall not exceed a maximum of 12 participants.

(7) Evaluation. The course shall include an evaluation method that documents that educational objectives have been met - e.g. written examination or written evaluation - and that provides for written follow-up evaluation at the conclusion of the longitudinal assessment.

Deletions to the regulatory text are indicated by double strike-through, thus: ~~deleted language~~. Additions to the regulatory text are indicated by a double underline, thus: added language.

(8) Records. The course provider shall maintain all records pertaining to the program, including a record of the attendance for each participant, for a minimum of 3 years and shall make those records available for inspection and copying by the board or its designee.

(9) Course Completion. The provider shall issue a certificate of completion to a participant who has successfully completed the program. The provider shall also notify the board or its designee in writing of its determination that a participant did not successfully complete the program. The provider shall fail a participant who either was not actively involved in the class or demonstrated behavior indicating a lack of insight (e.g., inappropriate comments, projection of blame). This notification shall be made within 10 calendar days of that determination and shall be accompanied by all documents supporting the determination.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4300, Business and Professions Code.

Deletions to the regulatory text are indicated by double strike-through, thus: ~~deleted language~~. Additions to the regulatory text are indicated by a double underline, thus: added language.

Attachment A-4

Specific Language to Add Title 16 CCR Section 1785
Self Assessment of a Veterinary Food Animal Drug Retailer

Add Section 1785 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1785. Self-Assessment of a Veterinary Food-Animal Drug Retailer by the Designated Representative-in-Charge.

(a) The designated representative-in-charge of each veterinary food-animal drug retailer as defined under section 4041 of the Business and Professions Code shall complete a self-assessment of the wholesaler's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the designated representative-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new veterinary food-animal drug retailer permit is issued, or

(2) There is a change in the designated representative-in-charge. The new designated representative-in-charge of a wholesaler is responsible for compliance with this subdivision.

(3) There is a change in the licensed location of a veterinary food-animal drug retailer to a new address.

(c) The components of this assessment shall be on Form 17M-40 entitled "Veterinary Food-Animal Drug Retailer Self-Assessment" which is hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.

(d) Each self-assessment shall be kept on file in the licensed premises for three years after it is completed.

(e) The veterinary food-animal drug retailer is jointly responsible with the designated representative-in-charge for compliance with this section.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4201, and 4196 Business and Professions Code.

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STATE AND CONSUMERS SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

VETERINARY FOOD-ANIMAL DRUG RETAILER SELF ASSESSMENT

All legal references used throughout this self-assessment form are explained on Page 17
All references to "drugs" throughout this self–assessment refer to dangerous drugs and dangerous devices as defined in Business & Professions Code (B&P) section 4022. (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf) Dangerous drug or dangerous device means any drug or device unsafe for self-use in humans or animals.

Definitions:

"Veterinary Food-Animal Drug Retailer" (vet retailer) is an area, place or premises, other than a pharmacy that holds a valid license from the California State Board of Pharmacy as a wholesaler and, in and from which veterinary drugs for food-producing animals are dispensed pursuant to a prescription from a licensed Veterinarian. It is a separate and additional license from a wholesaler license. Veterinary food–animal drug retailer includes but is not limited to any area, place or premises described in a permit issued by the board wherein veterinary food-animal drugs (as defined in Business & Professions Code section 4042) are stored, possessed, or repackaged, and from which veterinary drugs are furnished, sold, or dispensed at retail pursuant to a prescription from a licensed veterinarian.

'Veterinary Food–Animal Drugs" include any drug to be used in food-producing animals bearing the legend "Caution: federal law restricts this drug to use by or on the order of a licensed veterinarian" or words of similar import. Also included is any drug as defined in Section 14206 of the Food and Agriculture Code that is used in a manner that would require a veterinary prescription.

Veterinary Food-Animal Drug Retailer Name_____

Address_____

Phone_____

E-mail address (optional)_____

Ownership: Please mark one

☐ Sole owner ☐ Partnership ☐ Corporation ☐ LLC

☐ Non-licensed owner ☐ other (please specify) _____

CA Veterinary Food-Animal Drug Retailer Permit #_____ Expiration Date_____

CA Wholesaler Permit #_____ Expiration Date_____

DEA Registration #_____ Expiration Date_____

Date of most recent DEA Inventory_____

Hours: Daily _____Sat_____ Sun_____ 24 hours_____

Designated representative-in charge (DRIC) /pharmacist (RPH)_____

DRIC License # / RPH License #_____ Expiration Date_____

Licensed Veterinary Food-Animal Drug Retailer Staff (designated representative (DRep, pharmacist):

1._____DRep/RPH#_____ Exp. Date_____

2. _____ DRep/RPH#_____Exp. Date_____

Please mark the appropriate box for each question. If "NO," enter an explanation on the "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, add additional sheets.

1. Ownership/Location

Yes	No	N/A	
☐	☐	☐	Review the current veterinary food-animal drug retailer permit for this business. Are the listed owners correct and is the listed address correct? If either is incorrect, notify the board in writing. (B&PC 4196 [a] [d]) **Attach a copy of the notification letter to the board to this document.**

CORRECTIVE ACTION OR ACTION PLAN_____

_____

2. Facility

Yes	No	N/A	
☐	☐	☐	Are only pharmacists, intern pharmacists, designated representatives, and authorized officers of the law, or a person authorized to prescribe, permitted in the area place or premises described in the permit as a veterinary food-animal drug retailer without supervision? (B&P 4196[c])
☐	☐	☐	Is a pharmacist or designated representative responsible for any person who enters the premises for clerical, inventory control, housekeeping, delivery, maintenance, or similar functions related to the business of a veterinary food animal drug retailer? (B&P 4196[c])
☐	☐	☐	Are all veterinary food-animal drugs stored in a secure, lockable area? (B&P 4197[a][1])
			Premises, Fixtures and equipment: (B&P 4197[a][2])
☐	☐	☐	Fixtures and equipment -Clean and orderly
☐	☐	☐	Premises - dry
☐	☐	☐	Premises - well ventilated
☐	☐	☐	Premises - Adequately lighting

CORRECTIVE ACTION OR ACTION PLAN_____

_____

DRIC Initials _____

3. Designated Representative-in-Charge/Owner Responsibilities

Yes No N/A

☐☐☐ Are the owner and the designated representative-in-charge both equally responsible for maintenance of the records and inventory? (B&P 4081[b])

☐☐☐ Is the designated representative-in-charge responsible for the veterinary food-animal drug retailer's compliance with all state and federal laws related to practice as a veterinary food-animal drug retailer? (B&P 4196[d]).

☐☐☐ Has the owner notified the board within 30 days of the termination of the designated representative-in-charge or pharmacist? (B&P 4305.5[a])

☐☐☐ Has the owner identified and notified the board of the appointment of a new designated representative-in-charge within 30 days of the termination of the former designated representative-in-charge? (B & P 4196[d], 4331[b]. The appropriate form for this notification is a "Change of Designated Representative-in-Charge", which is available on the board's web site.

☐☐☐ Has any designated representative-in-charge who ends his or her employment at a wholesaler, notified the board within 30 days? (B & P 4305.5[c], 4101[b]. This notification is in addition to that required of the owner.

CORRECTIVE ACTION OR ACTION PLAN_____

_____

4. Designated Representative/Pharmacist

Yes No N/A

☐☐☐ Does your veterinary food-animal drug retailer operate only when a pharmacist or veterinary designated representative is on the premises? (4053[c])

☐☐☐ Is the address of the veterinary designated representative(s) current on their printed permit? (B&P4100,1704)

☐☐☐ If a veterinary designated representative or pharmacist changes his/her name or personal address of record, he/she will notify the board in writing within 30 days? (B&P 4100, CCR 1704)

☐☐☐ A pharmacist or veterinary retailer designated representative only dispenses drugs for use on food-producing animals on the basis of a written, electronically transmitted or oral order received from a licensed veterinarian? (CCR 1780.1[d])

☐☐☐ Only a pharmacist or the veterinary designated representative receives an oral order for a veterinary food-animal drug from the veterinarian? (CCR 1780.1[d])

DRIC Initials _____

Yes No N/A

☐☐☐ A written copy of any oral prescription is sent or electronically transmitted to the prescribing veterinarian within 72 hours? (CCR 1780.1[d])

CORRECTIVE ACTION OR ACTION PLAN_____

_____

5. Ordering Drugs by this Business for Future Sale/Transfer or Trade

Yes No N/A

☐☐☐ Are drugs ordered only from a business licensed by this board or from a licensed manufacturer? (B&P 4163[b], 4169)

CORRECTIVE ACTION OR ACTION PLAN_____

_____

6. Receipt of Drugs by this Business

Yes No N/A

☐☐☐ When drugs are received by your business, are they delivered to the licensed wholesale premises, and received by and signed for only by a designated representative or a pharmacist? (B&P 4059.5[a])

CORRECTIVE ACTION OR ACTION PLAN_____

_____

7. Drug Stock

Yes No N/A

☐☐☐ Is all drug stock open for inspection during regular business hours? (B&P 4081[a])

☐☐☐ Do all drugs you sell conform to the standards and tests for quality and strength provided in the latest edition of United States Pharmacopoeia or Sherman Food Drug and Cosmetic Act? (B&P 4342[a])

☐☐☐ If dangerous drugs, legend drugs or extra label use drugs are returned to the veterinary food-animal drug retailer from a client are they treated as damaged or outdated prescription drugs and stored in the quarantine area specified in California Code of Regulations section 1780(3)(1) and are not returned to stock, or dispensed, distributed or resold? (CCR 1780.1)

DRIC Initials _____

CORRECTIVE ACTION OR ACTION PLAN_____

_____

8. Prescription Dispensing

Yes No N/A

☐☐☐ Are dangerous drugs and extra label use drugs for use on food producing animals dispensed to clients pursuant to a prescription written by a veterinarian? (CCR 1780.1[a][d])

☐☐☐ Are dangerous drugs, and extra label use drugs prepared and labeled by a pharmacist or designated representative only? (CCR 1781.1[d])

☐☐☐ A veterinarian's prescription for a food-producing animal can only be refilled if the initial prescription issued indicated a specific number of refills. If no refills are indicated on the initial prescription, no refills may be dispensed. Instead a new prescription must be obtained from the veterinarian? (CCR 1780.1[g][1])

☐☐☐ No veterinary food-animal drug prescriptions are refilled over six months from the date of issuance of the initial order? (CCR 1780.1[g][2])

☐☐☐ Are prescriptions partially filled? If unable to fill the full quantity of drugs prescribed, fill and ship a portion of the order, so long as the full quantity is shipped within 30 days? (CCR 1780.1[j])

When partially filling a prescription, does the pharmacist or veterinary designated representative note the following information on the written prescription for each date the drugs are shipped: (CCR 1780.1[j])

☐☐☐ Quantity shipped?

☐☐☐ Date shipped?

☐☐☐ Number of containers shipped?

☐☐☐ If multiple containers, each container must be sequentially numbered?

☐☐☐ If unable to fill the full quantity of a prescription within 30 days, has a new veterinarian's prescription been written to fill the remainder of the drugs originally prescribed? (CCR 1780.1[j])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

DRIC Initials _____

9. Prescription Labeling

Yes No N/A

☐☐☐ Does only a pharmacist or veterinary designated representative prepare and affix the label to a veterinary food-animal drug product?

Pursuant to a veterinarian's prescription, are prescription labels affixed to all drug containers that include: (CCR 1780.1[h][1-14])

☐☐☐ Active ingredients or the generic name(s) of the drug?

☐☐☐ Manufacturer of the drug?

☐☐☐ Strength of the drug dispensed?

☐☐☐ Quantity of the drug dispensed?

☐☐☐ Name of the client?

☐☐☐ Species of food-producing animal for which the drug is described?

☐☐☐ Condition for which the drug is prescribed?

☐☐☐ Directions for use?

☐☐☐ Withdrawal time?

☐☐☐ Cautionary statements, if any?

☐☐☐ Name of the veterinarian prescriber?

☐☐☐ Date dispensed?

☐☐☐ Name and address of the veterinary food-animal drug retailer?

☐☐☐ Prescription number or another means of identifying the prescription?

☐☐☐ If an order is filled in multiple containers, a sequential numbering system to provide a means to identify multiple units if shipped to the same client from the same prescription? (container 1 of 6, container 2 of 6)

☐☐☐ Manufacture's expiration date?

CORRECTIVE ACTION OR ACTION PLAN_____

_____

10. Repackaging

Definition - Repackaging within the meaning of B&P 4041 means that a veterinary food-animal drug retailer may break down case lots of dangerous drugs as described in 4022(a) or extra label use drugs, so long as the seals on the individual containers are not broken.

Yes No N/A

☐☐☐ Are only sealed original manufacturer's containers labeled for distribution to clients? Veterinary retailers or wholesalers cannot open a container and count out or measure out any quantity of a dangerous legend or extra label use drug. (CCR 1780.1[b])

DRIC Initials _____

CORRECTIVE ACTION OR ACTION PLAN_____

_____

11. Sale or Transfer of Drugs by this Business

Yes	No	N/A	
☐	☐	☐	Are all dangerous drugs and extra label drugs that are sold, only sold pursuant to a prescription issued by a veterinarian to a veterinarian's client for use on food-producing animals? (CCR 1780.1[a])
☐	☐	☐	No dangerous drugs or extra label drugs are sold, traded or transferred at wholesale by the veterinary retailers? (B&P 4041)
☐	☐	☐	Are practices in place to prevent dangerous drugs from being sold, traded or transferred if the vet retailer or wholesaler knew or reasonably should have known the drugs were adulterated as defined by CA Health & Safety Code section 111250, misbranded as defined by CA Health & Safety Code section 111335, or beyond the use date on the label? (B&P 4169[a])
☐	☐	☐	List any incidents where adulterated, misbranded or expired drugs were purchased, sold, traded or transferred by this business in the past 2 years.

_____

_____

☐	☐	☐	Do your advertisements for dangerous drugs or devices contain false, fraudulent, misleading or deceptive claims? (B&P 4341, 4651, CCR 1766)
☐	☐	☐	Do you offer any rebates, refunds, commissions or preferences, discounts, or other considerations for referring clients? If your business has any of these arrangements, please list with whom? (B&P 650)

_____

_____

If your business sells, transfers or delivers dangerous drugs outside of California, either to another state within the United States or a foreign country, do you comply with:

☐	☐	☐	All CA pharmacy and veterinary laws related to the distribution of drugs?
☐	☐	☐	The pharmacy law and veterinary laws of the receiving state within the United States?
☐	☐	☐	The statutes and regulations of the Federal Food and Drug Administration and the Drug Enforcement Administration?
☐	☐	☐	All laws of the receiving foreign country related to drugs for food producing animals?

DRIC Initials _____

Yes No N/A

☐☐☐ All applicable federal regulations regarding the exportation of dangerous drugs?

Describe how you determine a client in a foreign country is authorized to receive dangerous drugs or dangerous devices. (B&P 4059.5[e])

_____

_____

CORRECTIVE ACTION OR ACTION PLAN_____

_____

12. Delivery of Drugs

Yes No N/A

☐☐☐ Upon delivery of appropriately labeled prescription drugs or extra label drugs to a client, pursuant to a veterinarian's prescription, do you obtain the signature of the client, or the client's agent, on the invoice with notations of any discrepancies, corrections or damage? (CCR 1780.1[k])

CORRECTIVE ACTION OR ACTION PLAN_____

_____

13. Controlled Substances

Yes No N/A

☐☐☐ If a controlled substance is dispensed, are the labels on the containers countersigned by the prescribing veterinarian before being provided to the client? (CCR1780.1[e])

Note: Please refer to "Controlled Substances" section of the Wholesaler Self Assessment for additional controlled substance statutes, regulations, and requirements your business must follow

CORRECTIVE ACTION OR ACTION PLAN_____

_____

14. Consultant Pharmacist

Yes No N/A

☐☐☐ Does your consulting pharmacist assure compliance with all statutes and regulations governing veterinary food-animal drug retailers? (B&P 4198[e])

DRIC Initials _____

Yes No N/A

☐☐☐ Does your consultant pharmacist visit routinely, but at least quarterly? (B&P 4198[e])

Does your consultant pharmacist: (B&P 4198[e])

☐☐☐ Review and revise policies and procedures?

☐☐☐ Assure compliance with state and federal statutes and regulations for labeling, storage and dispensing of veterinary food-animal drugs?

☐☐☐ Provide a written report twice yearly certifying whether or not the veterinary food-animal drug retailer is operating in compliance with the requirements of this chapter?

☐☐☐ Are these written reports readily available for inspection upon request?

CORRECTIVE ACTION OR ACTION PLAN_____

_____

15. Designated Representative Training.

Yes No N/A

☐☐☐ Does your business prepare and maintain records of training and demonstrated competence for each individual employed or retained by you? (B&P 4198[b])

☐☐☐ Are records of training and demonstrated competence for each employee maintained for 3 years after the last date of employment? (B&P 4198[b])

CORRECTIVE ACTION OR ACTION PLAN_____

_____

16. Quality Assurance Program

Does your business have an ongoing, documented quality assurance program, which includes but is not limited to: (B&P 4198 [c])

Yes No N/A

☐☐☐ Monitoring personnel performance?

☐☐☐ Storage of veterinary food-animal drugs?

☐☐☐ Maintenance of equipment?

☐☐☐ Dispensing of veterinary food-animal drugs?

CORRECTIVE ACTION OR ACTION PLAN_____

_____

DRIC Initials _____

17. Policies and Procedures

Does your business maintain and adhere to policies and procedures for: (B&P 4198)

Yes No N/A

- ☐☐☐ Handling of veterinary food animal drugs?
- ☐☐☐ Dispensing of veterinary food animal drug?
- ☐☐☐ Staff training records?
- ☐☐☐ Cleaning of equipment?
- ☐☐☐ Storage and maintenance of veterinary food –animal drugs?
- ☐☐☐ Storage and maintenance of equipment?
- ☐☐☐ Record keeping requirements?
- ☐☐☐ Storage requirements?
- ☐☐☐ Security requirements?
- ☐☐☐ Quality assurance?

CORRECTIVE ACTION OR ACTION PLAN_____

_____

18. Record Keeping Requirements

Purchase and Sales Records

Yes No N/A

☐☐☐ Are all records of acquisition and disposition of dangerous drugs, retained on the premises, open for inspection, during regular business hours? (B&P 4081, 4332, CCR 1718)

☐☐☐ Are all prescription documents and other disposition records for dangerous drugs or extra label use drugs dispensed by a vet food-animal drug retailer kept on file and maintained on the premises for 3 years? (B&P 4198[b])

☐☐☐ Are all records of prescription refills retained by your business on the premises for 3 years? (CCR1780.1[I], B&P 4081[a], 4332)

☐☐☐ Are all purchase and sales records retained in a readily retrievable form? (B&P 4105[a])

Yes No N/A

☐☐☐ Are records of shipment of labeled dangerous drugs to clients (also known as an expanded invoice) included in the client's shipment? This document includes: (CCR1780.1[i])

- ☐☐☐ Drug name?
- ☐☐☐ Quantity shipped?
- ☐☐☐ Manufacturer's name and lot number?

DRIC Initials _____

Yes No N/A

☐☐☐ Date of shipment?

☐☐☐ Name of the pharmacist or vet retailer exemptee who is responsible for the distribution?

☐☐☐ Are copies of the records of shipment (also known as the expanded invoice) distributed to the prescribing veterinarian? (CCR 1780.1 [i])

☐☐☐ Are copies of the records of shipment (also known as the expanded invoice) of labeled dangerous drugs retained by your business for 3years? (CCR 1780.1[I])

Inventory

Yes No N/A

☐☐☐ Is a current, accurate inventory maintained for all dangerous drugs (B&P 4081[a], CCR 1718)

Consultant Pharmacist

Yes No N/A

☐☐☐ Are consultant pharmacist semi-annual reports retained by your business for 3 years from the making? (B&P 4198 [e])

Quality Assurance

Yes No N/A

☐☐☐ Is quality assurance documentation retained for 3 years from the making? (B&P 4198[d])

Policies and Procedures

Yes No N/A

☐☐☐ Are all policies and procedures specified in section 4198(a) maintained for 3 years from the making? (B&P 4198(b)

☐☐☐ Are all policies and procedures, documents related to the quality assurance program, and all records of employee training and demonstrated competency open for inspection by authorized officers of the law? (B&P 4198[b])

Temporary removal of records

Yes No N/A

☐☐☐ If you temporarily remove purchase or sales records from your business, does your business retain, on your licensed premises at all times, a photocopy of each record temporarily removed? (B&P 4105[b])

DRIC Initials _____

Off-site storage waiver

Yes No N/A

☐☐☐ Are required records stored off-site only if a board issued written waiver has been granted? (CCR 1707[a])

☐☐☐ If your business has a written waiver, write the date the waiver was approved and the off-site address where the records are stored below: (CCR 1707[a])

_____

_____

Yes No N/A

☐☐☐ If an off-site written waiver is in place, is the storage area secure from unauthorized access? (CCR 1707[b][1])

☐☐☐ If an off-site waiver is in place, are the records stored off-site retrievable within 2 business days? (1707[b][1])

CORRECTIVE ACTION OR ACTION PLAN_____

_____

19. Reporting Requirements to the Board

Ownership

Yes No N/A

☐☐☐ I understand this veterinary retailer license is not transferable to a new owner. A change of ownership must be reported to this board, as soon as the parties have agreed to the sale. Before the ownership actually changes, an additional application for a temporary permit must be submitted, in addition to an application for a permanent new permit, to the board, if the new owner wants to conduct business while the board is processing the change of ownership application and until the new permanent permit is issued. A company cannot transfer the ownership of the business via a contract with another individual or business, without the board's approval. (B&P 4201[h][I], 4196[b], CCR 1709[b])

☐☐☐ Are transfers, in a single transaction or a series of transactions, of 10% or more of the beneficial interest in a business licensed by the board to a person who did not hold beneficial ownership interest at the time of the initial permit was issued, reported in writing to the board within 30 days of the transaction? (CCR 1709[b])

☐☐☐ Any transfer of a beneficial interest in a business licensed by the board, in a single transaction or series of transactions, to a person or entity, which results in the transferee holding 50% or more shall constitute of change of ownership and an application must be submitted to the board for a change of ownership. (CCR 1709 [c])

DRIC Initials _____

Yes No N/A

☐☐☐ When called upon by an inspector, can the business owner or manager, produce information indicating the names of the business owners, managers and employees and a brief statement of the capacity for each person employed by the business? (B&P 4082)

Veterinarian

Yes No N/A

☐☐☐ Whenever a veterinary designated representative dispenses to the same client for use on the same production class of food-animals, dangerous drugs, or extra label use drugs prescribed by multiple veterinarians, does the veterinary designated representative contact the prescribing veterinarians for authorization before dispensing any drugs? (CCR 1780.1[f])

☐☐☐ Are copies of expanded invoices, documenting sales of dangerous drugs, distributed to the prescribing veterinarian within 72 hours of dispensing? (CCR 1780.1[I]).

☐☐☐ Is a written copy of any oral prescription received by either a pharmacist or designated representative of the veterinary food-animal drug retailer sent or electronically transmitted to the prescribing veterinarian within 72 hours? (CCR 1780.1[d])

Consultant Pharmacist

Yes No N/A

☐☐☐ Does the consultant pharmacist provide written certification every 6 months that your business is or is not in compliance with all applicable statutes and regulation? (B&P 4198[e])

☐☐☐ Does your business submit the most recent consultant pharmacist report with the annual application to renew the veterinary food-animal drug retailer license with this board? (B&P 4198[e])

Designated Representative in Charge/ Designated Representative

Yes No N/A

☐☐☐ If a designated representative-in-charge terminates employment at this business, does the business notify the board within 30 days of the termination? (B&P 4101[b], 4305.5[c])

☐☐☐ When a veterinary designated representative leaves the employ of a veterinary food-animal drug retailer, would the business owner immediately return the exemptee license to the Board of Pharmacy? (CCR 1780.1[l])

☐☐☐ When a designated representative in charge terminates employment at this business, does the designated representative in charge notify the board within 30 days of the termination.? This requirement is in addition to the requirement for the owner to notify this board. (B&P 4101[c])

DRIC Initials _____

Discontinuation of Business

Yes No N/A

☐☐☐ I understand if this business is discontinued, the owner must notify the board in writing before the actual discontinuation of business? (CCR 1708.2).

☐☐☐ I understand the owner of this business must immediately notify the board in writing if any assignment is made for the benefit of creditors, if the business enters into any credit compromise arrangement, files a petition in bankruptcy, has a receiver appointed, or enters into liquidation or any other arrangement that might result in the sale or transfer of drugs? (CCR 1705)

Controlled substances (if applicable)

Yes No N/A

☐☐☐ Does the owner report to the board within 30 days of discovery, any loss of controlled substances, including amounts and strengths of the missing drugs? (CCR 1715.6)

☐☐☐ Does the owner notify the DEA, on a DEA form 106, of any theft or significant loss of controlled substances upon discovery? (CFR 1301.74[c])

☐☐☐ Do your employees know about their obligation to report any known diversion or loss of controlled substances to a responsible person within your business? (CFR 1301.91)

Yes No N/A

☐☐☐ If the business holds a DEA registration, does the owner understand the requirement to notify the DEA promptly of the discontinuation of the business and all unused DEA 222 order forms must be returned to the DEA? (CFR1301.52[a], 1305.14)

CORRECTIVE ACTION OR ACTION PLAN_____

_____

20. Additional Licenses/Permits Required

List all licenses and permits required to conduct this business, including local business licenses, wholesaler licenses held in other states, permits or licenses required by foreign countries or other entities (B&P 4107, 4059[a], CFR 1305.11[a])

_____

_____

_____

DRIC Initials _____

Designated Representative-in-Charge/Pharmacist Certification:

DESIGNATED REPRESENTATIVE-IN-CHARGE CERTIFICATION

I, (Please print) _____, RPH # _____ hereby certify that I have completed the self-assessment of this veterinary food-animal drug retailer of which I am the designated representative-in-charge. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury that the information contained in this self-assessment form is true and correct.

Signature _____ Date _____
(Designated Representative-in-Charge)

Legal References used in the self-assessment forms (California Code of Regulations [CCR], Title 16 and Title 24, and Business and Professions Code [B&P], Chapter 9, Division 2) can be found in the *California Pharmacy Law* (below) or visit the Board of Pharmacy Web site at www.pharmacy.ca.gov under *California Pharmacy Law and Index.*

The Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act is also in the *California Pharmacy Law* (below) or you can visit the Board of Pharmacy Web site at www.pharmacy.ca.gov under *California Pharmacy Law and Index.*

California Code of Regulations (CCR), Chapter 1, Division 5, Title 22, and other references can be found in the California State Law Library or county law libraries.

Code of Federal Regulations (CFR), Title 21, Chapter II, Drug Enforcement Administration, may be found at www.dea.gov.

California Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento CA 95834
(916) 574-7900
fax: (916) 574-8618
www.pharmacy.ca.gov

California Pharmacy Law may be obtained by contacting:
Law Tech
1060 Calle Cordillera, Suite 105
San Clements CA 92673
(800) 498-0911 Ext. 5
www.lawtech-pub.com

Pharmacist Recovery Program
(800) 522-9198 (24 hours a day)

Atlantic Associates, Inc. (CURES)
Prescription Collection
8030 S. Willow Street, Bldg. III, Unit 3
Manchester NH 03103
Phone: (888) 539-3370
Fax: 877-508-6704

Bureau of Narcotic Enforcement
Security Prescription and CURES Programs
1102 Q Street, 6th Fl.
Sacramento, CA 95817
(916) 319-9062
Fax: (916) 319-9448
http://www.ag.ca.gov/bne

CURES Patient Activity Report Request Forms:
http://www.ag.ca.gov/bne/trips.php

PRESCRIBER BOARDS:

Medical Board of California
1426 Howe Avenue, Suite 54
Sacramento CA 95825
(800) 633-2322
(916) 263-2499
Fax: (916) 263-2387
http://www.mbc.ca.gov

Dental Board of California
1432 Howe Ave. #85
Sacramento, CA 95825
(916) 263-2300
fax: (916) 263-2140
http://www.dbc.ca.gov

Board of Registered Nursing
1625 N. Market Blvd., Suite N217
Sacramento, CA 95834
(916) 322-3350
fax: (916) 574-8637
http://www.rn.ca.gov/

Board of Optometry
2420 Del Paso Road, Suite 255
Sacramento, CA 95834
(916) 575-7170
fax: (916) 575-7292
http://www.optometry.ca.gov/

Osteopathic Medical Board of California
2720 Gateway Oaks Drive, #350
Sacramento, CA 95833
(916) 263-3100
fax: (916) 263-3117
http://www.ombc.ca.gov

Physician Assistant Committee
1424 Howe Avenue, #35
Sacramento, CA 95825
(916) 561-8780
fax: (916) 263-2671
http://www.physicianassistant.ca.gov

Board of Podiatric Medicine
1420 Howe Avenue, #8
Sacramento, CA 95825
(800) 633-2322
(916) 263-2647
fax: (916) 263-2651
http://www.bpm.ca.gov

Veterinary Medical Board
1420 Howe Avenue, #6
Sacramento, CA 95825
(916) 263-2610
fax: (916) 263-2621
http://www.vmb.ca.gov

FEDERAL AGENCIES:

Food and Drug Administration – Industry Compliance
http://www.fda.gov/oc/industry/centerlinks.html#drugs

The **Drug Enforcement Administration** may be contacted at:

DEA Website:
http://www.deadiversion.usdoj.gov

Online Registration – New Applicants:
http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm

Online Registration - Renewal:
www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm

Registration Changes (Forms):
http://www.deadiversion.usdoj.gov/drugreg/change_requests/index.html

DEA Registration Support (all of CA):
(800) 882-9539

Online DEA 106 Theft/Loss Reporting:
https://www.deadiversion.usdoj.gov/webforms/app106Login.jsp

Online DEA 222 Controlled Substance Ordering System (CSOS):
http://www.deaecom.gov/

DEA - Fresno
2444 Main Street, Suite 240
Fresno, CA 93721
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: (559) 487-5402

DEA - Los Angeles
255 East Temple Street, 20th Floor
Los Angeles CA 90012
(888) 415-9822 or (213) 621-6960 (Registration)
(213) 621-6942 or 6952
(Diversion or Investigation)

DEA – Oakland
1301 Clay Street, Suite 460N
Oakland, CA 94612
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: (510) 637-5600

DEA – Redding
310 Hensted Drive, Suite 310
Redding, CA 96002
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: (530) 246-5043

DEA - Riverside
4470 Olivewood Avenue
Riverside, CA 92501-6210
Registration: (888) 415-9822 or
(213) 621-6960
Diversion or Investigation: (909) 328-6000 or
(909) 328-6200

DEA - Sacramento
4328 Watt Avenue
Sacramento CA 95821
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: (916) 480-7100 or
(916) 480-7250

DEA – San Diego and Imperial Counties
4560 Viewridge Avenue
San Diego, CA 92123-1637
Registration: (800) 284-1152
Diversion or Investigation: (858) 616-4100

Attachment A-5

Specific Language to Add Section 1751.8
Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

Add Section 1751.8 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.8 – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

(a) Agencies seeking to become approved accrediting agencies for pharmacies that compound sterile injectable drugs pursuant to Business and Professions Code section 4127.1, shall provide evidence satisfactory to the board that:

(1) The accrediting agency performs site inspections and re-accreditation reviews of each accredited pharmacy at least every three years.

(2) The standards for granting accreditation and scoring guidelines for those standards reflect California law and sound professional practice as established by nationally recognized professional or standard-setting organizations.

(3) The surveyors who perform site inspections possess qualifications necessary to evaluate the professional practices subject to accreditation.

(4) The accrediting agency is recognized by at least one California healthcare payors (e.g., HMOs, PPOs, PBGH, CalPERS).

(5) The accrediting agency is able to accredit California and non-resident pharmacies.

(b) An agency seeking recognition from the board to become an approved accrediting agency must submit a comparison of the agency's sterile compounding standards with each of the components of this article and other California law regarding sterile injectable compounding. The applicant agency's request will not be processed unless the comparison demonstrates the agency's standards are in compliance with California Pharmacy Law.

(c) The board shall consider the length of time the agency has been operating as an accrediting agency.

(d) The board shall be able to obtain access to an approved accrediting agency's report on individual pharmacies.

(e) On an annual basis, no later than July 1 of each year, an approved accrediting agency will submit a report to the board listing all board- licensed facilities that have been accredited during the past 12 months.

(f) The board may conduct unannounced inspections of accredited sites to determine if the licensed facility is in compliance with California law and good professional practice.

(g) This approval shall be good for a period of three years. Three months before the end of the approval period, an approved accrediting agency must submit a reapplication to the board for continued recognition as an approved accrediting agency. The Board of Pharmacy shall take action on a completed application at a scheduled board meeting.

Specific Language to Amend Sections 1721 and 1723.1
Dishonest Conduct on a Pharmacist Licensure Examination/Confidentiality

Amend Section 1721 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1721. Dishonest Conduct During Examination.

An applicant for examination as a pharmacist who engages in dishonest conduct during the examination shall not have that examination graded, shall not be approved to take the examination for ~~twelve months~~ three years from the date of the incident, and shall surrender his or her intern ~~card~~ license until eligible to take the examination. The applicant may not be issued a pharmacy technician license until the applicant is again eligible to take the examination.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4200, Business and Professions Code.

Amend Section 1723.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1723.1. Confidentiality of Examination Questions.

Examination questions are confidential. Any applicant for any license issued by the board who removes all or part of any qualifying examination from the examination room or area, or who conveys or exposes all or part of any qualifying examination to any other person may be disqualified as a candidate for a license. The applicant shall not be approved to take the examination for three years from the date of the incident and shall surrender his or her intern license until again eligible to take the examination. The applicant may not be issued a pharmacy technician license until the applicant is again eligible to take the examination.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 123 and 496, Business and Professions Code.